

US3062151 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:04:29

All time stamps listed in this document are displayed in GMT

US3062151

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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Participant ID

US3062151

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

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US3062151

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Date of Informed Consent (*dd MMM yyyy*) 7 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	INCONTINENCE, URINARY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	OSTEOARTHRITIS, BILATERAL HIPS
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	OSTEOARTHRITIS BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	OSTEOPENIA
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 (7)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	SPINAL STENOSIS
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 (8)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	ARTHRALGIA, GENERALIZED
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	LEG CRAMPS, RECURRENT
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 (11)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

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



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Condition	NEUROPATHY, SENSORY
Start date (dd MMM yyyy)	UN JAN 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:35
Height (xxx.x)	163.0 cm
Weight (xxx.x)	71.6 kg
BMI (xxx.x)	26.94870 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 type="radio"/>
If Other, specify	
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) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 01 JAN 2005

Date of last menstruation unknown False

US3062151

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:34:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185226

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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)	07 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:45
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 13:25
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 12:51

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	07 AUG 2020
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Collection time (00:00-23:59)	12:05 (24 HR)
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Collection date and time (derived)	07 AUG 2020 12:05
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:09	07 AUG 2020 12:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

07 AUG 2020 13:29

PC Open Date & Time

07 AUG 2020 13:11

PC Close Date & Time

07 AUG 2020 15:41

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

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

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 AUG 2020 16:36

PC Close Date & Time

08 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

08 AUG 2020 15:26

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

09 AUG 2020 14:05

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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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

98.2 °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

10 AUG 2020 14:37

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PC Open Date & Time

10 AUG 2020 12:00

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PC Close Date & Time

11 AUG 2020 11:59

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US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

11 AUG 2020 13:59

---

PC Open Date & Time

11 AUG 2020 12:00

---

PC Close Date & Time

12 AUG 2020 11:59

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US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 AUG 2020 13:58

---

PC Open Date & Time

12 AUG 2020 12:00

---

PC Close Date & Time

13 AUG 2020 11:59

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US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 14:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**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

07 AUG 2020 13:30

PC Open Date & Time

07 AUG 2020 13:11

PC Close Date & Time

07 AUG 2020 15:41

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 AUG 2020 16:36

PC Close Date & Time

08 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**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

08 AUG 2020 15:26

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**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

09 AUG 2020 14:05

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

**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

10 AUG 2020 14:37

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

**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

11 AUG 2020 13:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

**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

12 AUG 2020 13:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**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

13 AUG 2020 14:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**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 ☐

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 13:31
PC Open Date & Time	07 AUG 2020 13:11
PC Close Date & Time	07 AUG 2020 15:41

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**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 ☐

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 16:36

PC Close Date & Time

08 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:29

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:27
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:29

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 09:14
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59



US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 14:38
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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 ☒

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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



US3062151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:12
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:39
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3062151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

04 SEP 2020 13:20

US3062151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:18	04 SEP 2020 13:18
Nasopharyngeal Swab 2	No		

US3062151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**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

98.3 °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

04 SEP 2020 14:41

PC Open Date & Time

04 SEP 2020 14:28

PC Close Date & Time

04 SEP 2020 16:58

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	04 SEP 2020 19:01
PC Open Date & Time	04 SEP 2020 17:53
PC Close Date & Time	05 SEP 2020 11:59



US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**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

100.3 °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

05 SEP 2020 18:52

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 SEP 2020 18:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:59

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:03

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**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

04 SEP 2020 14:41

PC Open Date & Time

04 SEP 2020 14:28

PC Close Date & Time

04 SEP 2020 16:58

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**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

04 SEP 2020 19:02

PC Open Date & Time

04 SEP 2020 17:53

PC Close Date & Time

05 SEP 2020 11:59



US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**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

05 SEP 2020 18:53

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**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

06 SEP 2020 18:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

**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

07 SEP 2020 18:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

**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

08 SEP 2020 19:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

**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

09 SEP 2020 19:08

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**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

10 SEP 2020 19:03

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**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 ☐

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 14:42
PC Open Date & Time	04 SEP 2020 14:28
PC Close Date & Time	04 SEP 2020 16:58



US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**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 ☐

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 19:03
PC Open Date & Time	04 SEP 2020 17:53
PC Close Date & Time	05 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:29

**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)

108 of 4470

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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

110 of 4470

EAB) (1725)

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:09
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:29

**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 ☒

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**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:04
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3062151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:37

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 10:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

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.*

US3062151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	02 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	10:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	02 OCT 2020 10:56
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US3062151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:34:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 OCT 2020 07:38:45
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 04:49:03

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 OCT 2020 16:08:56
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 NOV 2020 12:01:20
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 NOV 2020 12:19:49
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3062151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 106
Have 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	18 NOV 2020 17:12:17
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	19 NOV 2020 17:33:18
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

23 NOV 2020 18:39:01

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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 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	29 NOV 2020 07:40:38
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 13:45:32

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 10:54:10

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 11:44:33

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 12:45:57

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

03 JAN 2021 12:30:56

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 10:13:53
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

18 JAN 2021 13:25:03

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

24 JAN 2021 11:51:24

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

02 FEB 2021 19:06:02

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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

07 FEB 2021 11:48:09

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 09:28:53
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 09:00:10

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 20:26:15

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 11:15:40

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 12:42:46

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 15:29:35

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 09:58:30

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 11:59:30

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 10:29:42

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

Date and time of submission

18 APR 2021 15:32:55

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 13:31:08

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

Date and time of submission

02 MAY 2021 20:24:23

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐ 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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 NOV 2021 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐ 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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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°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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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 <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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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="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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**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 ☐  
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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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 <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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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"/>

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

**US3062151**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 15:04:29**

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		28 FEB 2021 20:26:28

US3062151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3062151

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

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

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3062151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 13:31
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062151

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

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.*

US3062151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

13:47 (24 HR)

Collection date and time (derived)

22 MAR 2021 13:47

US3062151

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:21:06

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062151

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:21:06

Generated On: 09 Jun 2021 15:04:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3062151**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

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*

**US3062151**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3062151**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:04:29**

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"/>

**US3062151**

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

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

**Generated On: 09 Jun 2021 15:04:29**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3062151

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3062151

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Date of updated informed consent (dd MMM yyyy) 29 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 29 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3062151

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

11:03 (24 HR)

Collection date and time (derived)

29 JAN 2021 11:03

US3062151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:38:37

Generated On: 09 Jun 2021 15:04:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00 - 23:59)

11:00

Collection Date and Time (derived)

29 JAN 2021 11:00

US3062151

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:59:38

Generated On: 09 Jun 2021 15:04:29

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3062151

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	USA-US090-2020-MRNA-1273-P30 1000005
Adverse event	LEFT HIP OSTEOARTHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 OCT 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)	14 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	15 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

331 of 4470



US3062151

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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DURING SCREENING, SUBJECT  
REPORTED THAT A LEFT HIP  
REPLACEMENT WAS PLANNED.  
SUBJECT HAD THE PROCEDURE  
ON 10/14/2020. SUBJECT  
ADMITTED TO HOSPITAL ON  
10/14/2020 AND PROCEDURE  
PERFORMED. SUBJECT WAS  
DISCHARGED FROM THE  
HOSPITAL IN STABLE  
CONDITION ON 10/15/2020.  
RELEASE OF RECORDS SENT TO  
HOSPITAL 10/20/2020  
11/25/2020 HOSPITAL RECORDS  
RECEIVED. MEDICATIONS  
UPDATED PER CONMED FORM.  
NO CHANGE IN OTHER  
INFORMATION PREVIOUSLY  
REPORTED.

---

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

---

US3062151

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	USA-US090-2020-MRNA-1273-P30 1000005
Adverse event	POST OP WOUND INFECTION, L HIP
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)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	28 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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US3062151

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

---

SUBJECT CONTACTED  
10/29/2020 FOR DAY 85 CALL.  
DURING CALL, SUBJECT  
REPORTS THAT SHE WAS  
RELEASED FROM THE  
HOSPITAL ON 10/28/2020.  
SUBJECT REPORTED THAT SHE  
WAS ADMITTED TO THE  
HOSPITAL ON 10/20/2020 FOR A  
POSTOPERATIVE WOUND  
INFECTION. DURING THE  
HOSPITALIZATION SHE HAD A  
REVISION TO HER LEFT HIP  
REPLACEMENT. THE LEFT HIP  
REPLACEMENT WAS  
PERFORMED ON 10/14/2020.  
RELEASE OF RECORDS MAILED  
TO SUBJECT.

---

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

---

US3062151

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

POST OPERATIVE PAIN,  
GENERALIZED

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3062151

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

POST OP NAUSEA RECURRENT

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 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 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

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EAB) (1725)



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	
Adverse event	CONSTIPATION, INTERMITTENT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 OCT 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 (5)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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)	

US3062151

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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)	

US3062151

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	USA-US090-2020-MRNA-1273-P30 1000005
Adverse event	NON CARDIAC CHEST 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)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 OCT 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)	21 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	28 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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PRIOR TO DISCHARGE ON  
23OCT2020 SUBJECT REPORTED  
CHEST PAIN. DECISION WAS  
MADE TO CANCEL DISCHARGE  
AND REPEAT TROPONIN AND  
ECG. TROPONIN RESULTS  
WERE NORMAL AND ECG  
SINUS TACHYCARDIA WITH  
POSSIBLE RIGHT BUNDLE  
BRANCH BLOCK ON 24OCT2020.  
MEDICAL RECORDS STATE  
THEY BELIEVE THE CHEST  
PAIN WAS POSSIBLY RELATED  
TO HER DUODENAL ULCER. ON  
24OCT2020, SUBJECT  
DEVELOPED 102.0 FEVER AND  
CONFUSION. SEE ADDITIONAL  
SAE.

---

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

---

US3062151

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

SUICIDAL IDEATION

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)

21 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 OCT 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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

GASTRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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



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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	
Adverse event	ESOPHAGITIS
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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 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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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

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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 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)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

EDEMA, LEFT LOWER  
EXTREMITY

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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 (15)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

SINUS TACHYCARDIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 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

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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



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Form: Adverse Events (16)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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AEID

Adverse event

HYPOTENSION

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 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

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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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 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)	_____

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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AEID

Adverse event

HEMATOMA LEFT HIP

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)

21 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 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

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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

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Form: Adverse Events (18)

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AEID

Adverse event

ABDOMINAL PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 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

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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

US3062151

Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	USA-US090-2020-MRNA-1273-P30 1000005
Adverse event	GASTROINTESTINAL BLEED
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 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)	21 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	28 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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



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SHE PRESENTED TO ER WITH WEAKNESS, BLOOD IN STOOL, AND SYNCOPE EPISODE. EGD ON 22 OCT 2020 REVEALED A HIATAL HERNIA, DUODENITIS, AND MILD GASTRITIS. CT PERFORMED ON 21 OCT 2020 SHOWED COLONIC DIVERTICULOSIS WITHOUT EVIDENCE OF ACUTE DIVERTICULITIS AND HEMATOMA OVERLAYING LEFT HIP. SUBJECT TO BE DISCHARGED ON 23 OCT 2020 IN STABLE CONDITION WHEN SHE REPORTED CHEST PAIN. DURING HOSPITALIZATION, PATIENT RECEIVED BLOOD TRANSFUSIONS DUE TO LOSS OF BLOOD. SEE ADDITIONAL SAES REGARDING CHEST PAIN AND POP UP WOUND INFECTION, LEFT HIP.

---

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 (20)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

EXCORIATION, LEFT HIP

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 OCT 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

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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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Form: Adverse Events (21)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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AEID

Adverse event

DUODENAL ULCER

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 DEC 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

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

DUODENITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 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

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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 (23)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

CONFUSION

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)

24 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 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

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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

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Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) 31 Mar 2021 20:59:36

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AEID

Adverse event

WEAKNESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 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

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Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

AEID

Adverse event

SYNCOPE EPISODE

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)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 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

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 31 Mar 2021 20:59:36

Generated On: 09 Jun 2021 15:04:29

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

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:38:37

Generated On: 09 Jun 2021 15:04:29

---

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

Yes ☒

No ☐

---

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

---



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TREXAR- DIETARY SUPPLEMENT

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS, BILATERAL HIPS AND KNEES

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 (1)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (2)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication CIRCUC-DEFENSE DIETARY SUPPLEMENT

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 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 (3)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication URIVARX

Prophylaxis Yes ☐  
No ☒

Indication INCONTINENCE, URINARY

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 (3)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication CELECOXIB

Prophylaxis Yes ☒  
No ☐

Indication OSTEOARTHRITIS BILATERAL  
HIPS AND KNEES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 OCT 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 (5)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROCODONE/ACETAMINOP  
HEN 5MG/325MG

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS, BILATERAL  
KNEES

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 (5)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	01 SEP 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 (6)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 26 SEP 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 (7)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROCODONE/ACETAMINOP  
HEN (7.5MG/325MG)

Prophylaxis Yes ☐  
No ☒

Indication POST OP PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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) 24 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication POST OP NAUSEA

Dose per administration 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PANTOPROZOLE

Prophylaxis Yes ☐  
No ☒

Indication POST OP NAUSEA

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 (10)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	20 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) 20 OCT 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 (11)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication SERTRALINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 (11)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN PAIN,  
GENERALIZED

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 (12)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

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 (13)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)		20 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) 28 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication POST OP WOUND 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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	28 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)	7 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 (18)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication POSTOPERATIVE WOUND  
INFECTION, LEFT HIP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	27 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)	28 OCT 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 (20)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 850

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

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

EVERY HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication ANCEF (CEFAZOLIN)

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITS

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 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 (23)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TRANEXAMIC ACID 1000MG/ML

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

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 (24)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

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 (25)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐  
No ☒

Indication POSTOPERATIVE NAUSEA  
RECURRENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication OXYCODONE/ACETAMINPHEN  
(10MG/325MG)

Prophylaxis Yes ☐  
No ☒

Indication POSTOPERATIVE PAIN,  
GENERALIZED

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 (27)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication SCOPOLAMINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 1.5

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 (28)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
HIPS

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 (29)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 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 (30)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication TORADOL

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

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 (30)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication OXYCODONE/ACETAMINOPHE  
N (5MG/325MG)

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIPS OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

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

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Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS BILATERAL  
HIPS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 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)

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Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 JAN 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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Name of Medication PEPCID

Prophylaxis Yes ☐  
No ☒

Indication POSTOPERATIVE NAUSEA

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 (36)

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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)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Name of Medication MORPHINE 10MG,  
DEXAMETHASONE 8MG,  
TORADOL 60MG, EPINEPHRINE  
1:1000 0.25ML, MARCAINE 0.25%  
30ML, NORMAL SALINE 30 ML

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITS

Dose per administration 1

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

Route of administration Oral ☐  
Topical ☐

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	14 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication OXYGEN THERAPY

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 1

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

If dose unit is Other, specify LITER PER MINUTE

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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Data signed: (b) (4) 02 Apr 2021 20:38:34

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 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)	25 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 (40)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION  
LEFT HIP

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)	27 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)	28 OCT 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 (43)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication COLACE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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) 28 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PACKED RED BLOOD CELLS

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

Dose per administration 1

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication MIRALAX

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 (45)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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) 26 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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 (47)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE,  
GENERALIZED

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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 (48)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE NAUSEA,  
RECURRENT

Dose per administration 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 (48)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

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 (50)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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 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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 (52)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication CEFEPIME

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)	24 OCT 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 (55)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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 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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TOBRAMYCIN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)	25 OCT 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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)		25 OCT 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 (60)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION

Dose per administration 0.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication ROCURONIUM

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication SUCCINYLCHOLINE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 (63)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication LIDOCAINE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)	25 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication THERA-M

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL DEFICIENCY

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 (65)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)	28 OCT 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 (66)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication VENOFR

Prophylaxis Yes ☐  
No ☒

Indication ANEMIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)		27 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)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

Dose per administration 1250

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 (67)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)	26 OCT 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 (68)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication ZOSYN

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 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)	26 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication SENOKOT S

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 50/8.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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) 26 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication VENOFR

Prophylaxis Yes ☐  
No ☒

Indication ANEMIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication MIDAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PERCOCET

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PERCOCET

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PROTONIX

Prophylaxis Yes ☐  
No ☒

Indication GASTROINTESTINAL BLEED

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 (74)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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) 21 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 (75)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication ASCORBIC ACID

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE INFECTION,  
LEFT HIP

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)	12 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication ALBUTEROL-IPRATROPIUM  
2.5-0.5 MG/ 3ML

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

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

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (77)

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	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)	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)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication	LACTATED RINGERS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST OPERATIVE INFECTION, LEFT HIP
Dose per administration	600
Dose unit	mg <input checked="" 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 type="radio"/>
If dose unit is Other, specify _____	
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 checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
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 (78)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) 02 Apr 2021 20:38:34

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Name of Medication LIDOCAINE 5%

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN,  
GENERALIZED

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 (79)

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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)		24 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)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication NICOTINE PATCH

Prophylaxis Yes ☒  
No ☐

Indication WITHDRAWAL PROPHYLAXIS

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 (80)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 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)	28 OCT 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) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication PNEUMOCOCCAL VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PNEUMONIA PROPHYLAXIS

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  
EAB) (1725)

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US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 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"/>

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTENSION

Dose per administration 100

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

If dose unit is Other, specify ML/HOUR

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 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)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

Name of Medication SODIUM BISPHOSPHATE  
ENEMA

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 133

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 02 Apr 2021 20:38:34

Generated On: 09 Jun 2021 15:04:29

	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 checked="" 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 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)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:38:37

Generated On: 09 Jun 2021 15:04:29

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:38:37

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 OCT 2020	LEFT HIP REPLACEMENT	Adverse Event	
24 OCT 2020	REVISION LEFT HIP REPLACEMENT	Adverse Event	
25 OCT 2020	IRRIGATION AND DEBRIDEMENT OF LEFT HIP	Adverse Event	
25 OCT 2020	EXCHANGE OF THE POLY AND FEMORAL HEAD OF THE IMPLANTS	Adverse Event	
23 OCT 2020	ELECTROCARDIOGRAM	Adverse Event	
22 OCT 2020	ESOPHAGOGASTRODUODENOSCOPY	Adverse Event	
21 OCT 2020	COMPUTERIZED TOMOGRAPHY SCAN, ABDOMINAL	Adverse Event	
26 OCT 2020	PICC LINE INSERTION	Adverse Event	

US3062151

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:04:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3062151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:04:29

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 ☐

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/OCT/2020 18:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 14:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 14:26
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



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/NOV/2020 16:50
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

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/FEB/2021 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/FEB/2021 13:56
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

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/MAR/2021 17:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 02 Apr 2021 20:38:38

Generated On: 09 Jun 2021 15:04:29

SAEID	USA-US090-2020-MRNA-1273-P301000005
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 16:07
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

US3062151 (Prod: Alliance for Multispecialty Research, LLC)

**US3062151**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:04:29**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:15:24
User entered 'US3062151'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:49:57

**US3062151**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:17:49
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:03:56
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:17:49
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:49:58

US3062151

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:17:49
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	07 Aug 2020 18:03:56
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'SCRN'	System	07 Aug 2020 18:03:56

US3062151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:04:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:49:59

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '72'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'YEARS'	System	07 Aug 2020 18:04:08

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '72'	System	07 Aug 2020 18:04:19

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered 'Female (F)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered 'I'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered empty.	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:29**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:25
User entered '0'	Janna Martinez (b) (4)	07 Aug 2020 18:04:08
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered '7 Aug 2020'	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Aug 2020'	System	07 Aug 2020 18:04:19

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2020'	System	07 Aug 2020 18:04:19

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered 'Amendment 1 (1)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered empty.	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered empty.	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered 'No (N)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:19
	(b) (4)	

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**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:36
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 16:49:58

**US3062151**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:29**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'I'	System	07 Aug 2020 18:04:23

**US3062151**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:04:29**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:40
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:23
	(b) (4)	

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 15:04:29**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:23:42
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:02:05
	(b) (4)	

US3062151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:13
Query 'Per DM CLR: Please note that there is no Con marissa Mueller 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. ' answered with 'per patient- conmed not prescribed' (Site from DM).	(b) (4) (b) (4)	10 Sep 2020 01:05:31
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:47
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
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. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:02:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 01:05:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 01:05:23
Data point term sent to Coder	System	09 Aug 2020 01:04:32
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Janna Martinez (b) (4) (b) (4)	09 Aug 2020 01:03:57

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'UN UNK 2018'	Janna Martinez (b) (4)	09 Aug 2020 01:03:57
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:03:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:03:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:03:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:03:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2018'	System	09 Aug 2020 01:03:57

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2018'	System	09 Aug 2020 01:03:57

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:03:57

**US3062151**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:03:57



US3062151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:04:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 01:06:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 01:06:24
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 01:04:44
User entered 'POST MENOPAUSAL'	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'UN UNK 2005'	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:04:16
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2005'	System	09 Aug 2020 01:04:16

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2005'	System	09 Aug 2020 01:04:16



**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:04:16

**US3062151**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:04:16

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Incontinence urinary - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 12:04:38
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:04:38
User closed query 'Per DM CLR: Please review and update the MH Condition to include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:23:36
Query 'Per DM CLR: Please review and update the MH Condition to include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated ' (Site from DM).	marissa Mueller (b) (4)	10 Sep 2020 01:06:04
Data point term sent to Coder	System	10 Sep 2020 01:06:04
Coding entries removed.	marissa Mueller (b) (4)	10 Sep 2020 01:06:01
User entered 'INCONTINENCE, urinary' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	10 Sep 2020 01:06:01
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:55
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and update the MH Condition to include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:03:14
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Incontinence, LLT: Incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 01:06:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 01:06:24
Data point term sent to Coder	System	09 Aug 2020 01:04:45
User entered 'INCONTINENCE'	Janna Martinez (b) (4) (b) (4)	09 Aug 2020 01:04:42

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'UN UNK 2017'	Janna Martinez (b) (4)	09 Aug 2020 01:04:42
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:04:42
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:04:42
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:04:42
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:04:42
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2017'	System	09 Aug 2020 01:04:42

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2017'	System	09 Aug 2020 01:04:42

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:04:42

**US3062151**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:04:42

US3062151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:43:17
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:43:17
Data point term sent to Coder	System	09 Aug 2020 01:05:57
User entered 'OSTEOARTHRITIS, BILATERAL HIPS'	Janna Martinez (b) (4)	09 Aug 2020 01:05:43
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'UN UNK 1990'	Janna Martinez (b) (4)	09 Aug 2020 01:05:43

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:05:43
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:05:43
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:05:43
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:05:43
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 1990'	System	09 Aug 2020 01:05:43

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**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '1990'	System	09 Aug 2020 01:05:43

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:05:43

**US3062151**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:05:43

US3062151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 01:08:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 01:08:24
Data point term sent to Coder	System	09 Aug 2020 01:07:09
User entered 'OSTEOARTHRITIS BILATERAL KNEES'	Janna Martinez (b) (4)	09 Aug 2020 01:06:06
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'UN UNK 1990'	Janna Martinez (b) (4)	09 Aug 2020 01:06:06
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:06:06
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:06:06

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:06:06
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:24:45
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:06:06
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 1990'	System	09 Aug 2020 01:06:06

**US3062151**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '1990'	System	09 Aug 2020 01:06:06

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:06:06



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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	09 Aug 2020 01:06:06

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Dec 2020 20:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 20:58:45
Data point term sent to Coder	System	17 Dec 2020 20:57:43
User entered 'Osteopenia'	Sherry Henning (b) (4)	17 Dec 2020 20:57:18

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 2000'	Sherry Henning (b) (4)	17 Dec 2020 20:57:18
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:57:18
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:57:18
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:57:18
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:57:18
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2000'	System	17 Dec 2020 20:57:18



**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2000'	System	17 Dec 2020 20:57:18

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:57:18

**US3062151**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:57:18

US3062151

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Dec 2020 20:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 20:58:45
Data point term sent to Coder	System	17 Dec 2020 20:57:43
User entered 'Spinal stenosis'	Sherry Henning (b) (4)	17 Dec 2020 20:57:40

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 2000'	Sherry Henning (b) (4)	17 Dec 2020 20:57:40
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:57:40
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:57:40
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:57:40
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:57:40
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2000'	System	17 Dec 2020 20:57:40

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2000'	System	17 Dec 2020 20:57:40

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:57:40

**US3062151**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:57:40

US3062151

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Dec 2020 20:59:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 20:59:56
Data point term sent to Coder	System	17 Dec 2020 20:58:44
User entered 'Arthralgia, generalized'	Sherry Henning (b) (4)	17 Dec 2020 20:58:37

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 2000'	Sherry Henning (b) (4)	17 Dec 2020 20:58:37
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:58:37
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:58:37
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:58:37
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:58:37
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2000'	System	17 Dec 2020 20:58:37

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2000'	System	17 Dec 2020 20:58:37

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:58:37

**US3062151**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:58:37

US3062151

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:00:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:00:43
	(b) (4)	
Data point term sent to Coder	System	17 Dec 2020 20:59:45
User entered 'low back pain'	Sherry Henning (b) (4)	17 Dec 2020 20:58:57
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 1990'	Sherry Henning (b) (4)	17 Dec 2020 20:58:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:58:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:58:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:58:57
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4) (b) (4)	15 Feb 2021 15:34:39
User entered '0'	(b) (4) Sherry Henning (b) (4) (b) (4)	17 Dec 2020 20:58:57

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 1990'	System	17 Dec 2020 20:58:57

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '1990'	System	17 Dec 2020 20:58:57

**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:58:57



**US3062151**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:58:57

US3062151

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Dec 2020 09:50:38
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 09:50:38
Data point term sent to Coder	System	17 Dec 2020 20:59:45
User entered 'leg cramps, recurrent'	Sherry Henning (b) (4) (b) (4)	17 Dec 2020 20:59:19

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**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 2000'	Sherry Henning (b) (4)	17 Dec 2020 20:59:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:59:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:59:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:59:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:59:19
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2000'	System	17 Dec 2020 20:59:19



**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2000'	System	17 Dec 2020 20:59:19

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:59:19

**US3062151**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:59:19

US3062151

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:01:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:01:46
	(b) (4)	
Data point term sent to Coder	System	17 Dec 2020 21:00:46
User entered 'Anxiety'	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 1990'	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 20:59:47
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 1990'	System	17 Dec 2020 20:59:47

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '1990'	System	17 Dec 2020 20:59:47

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:59:47

**US3062151**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 20:59:47

US3062151

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:01:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 21:01:46
	(b) (4)	
Data point term sent to Coder	System	17 Dec 2020 21:00:45
User entered 'depression'	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'un UNK 1990'	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	17 Dec 2020 21:00:04
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 1990'	System	17 Dec 2020 21:00:04

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '1990'	System	17 Dec 2020 21:00:04

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 21:00:04

**US3062151**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	17 Dec 2020 21:00:04

US3062151

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Jan 2021 21:28:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:28:25
Data point term sent to Coder	System	29 Jan 2021 21:28:21
User entered 'GERD'	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'UN Jan 2015'	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:27:17
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2015'	System	29 Jan 2021 21:27:17

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2015'	System	29 Jan 2021 21:27:17

**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	29 Jan 2021 21:27:17



**US3062151**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	29 Jan 2021 21:27:17

US3062151

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory neuropathy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	10 Mar 2021 10:53:48
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 10:53:48
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 21:07:10
Data point term sent to Coder	System	02 Mar 2021 21:29:00
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	02 Mar 2021 21:28:53
Coding entries removed.	(b) (4) Janna Martinez (b) (4)	02 Mar 2021 21:28:44
Signature has been broken.	(b) (4) Janna Martinez (b) (4)	02 Mar 2021 21:28:44
User entered 'NEUROPATHY, SENSORY' reason for change: Data Entry Error	(b) (4) Janna Martinez (b) (4)	02 Mar 2021 21:28:44

US3062151

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:04:29

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:01:16
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Jan 2021 21:30:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:30:23
Data point term sent to Coder	System	29 Jan 2021 21:29:21
User entered 'Neuropathy'	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'UN Jan 2012'	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:14
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:28:23
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'Jan 2012'	System	29 Jan 2021 21:28:23

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '2012'	System	29 Jan 2021 21:28:23

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	29 Jan 2021 21:28:23

**US3062151**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered empty.	System	29 Jan 2021 21:28:23

US3062151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

US3062151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

US3062151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User closed query 'Per source collection time of BMI is 11:35. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 19:25:58
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:25:57
Query 'Per source collection time of BMI is 11:35. Please verify and update if needed. ' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	10 Sep 2020 01:07:42
User entered '11:35' reason for change: Data Entry Error	(b) (4)	
	marissa Mueller (b) (4)	10 Sep 2020 01:07:38
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:38
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User opened query 'Per source collection time of BMI is 11:35. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 16:21:33
User entered '11:45'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered '07 Aug 2020 11:35'	System	10 Sep 2020 01:07:38
User entered '07 Aug 2020 11:45'	System	09 Aug 2020 01:08:20



US3062151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered '163.0' cm	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
DataPoint set to visible.	System	07 Aug 2020 18:04:23

US3062151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered '71.6' kg	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
DataPoint set to visible.	System	07 Aug 2020 18:04:23

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
Amendment Manager: User entered '26.94870'	System	16 Sep 2020 23:47:32
User entered '26.9'	System	09 Aug 2020 01:08:20
DataPoint set to visible.	System	07 Aug 2020 18:04:23

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'kg/m2'	System	09 Aug 2020 01:08:20
DataPoint set to visible.	System	07 Aug 2020 18:04:23

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
User entered '98.0' F	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
User entered '59'	(b) (4)	
	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	



**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'bpm'	System	09 Aug 2020 01:08:20

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
User entered '14'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'breaths/min'	System	09 Aug 2020 01:08:20

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
User entered '129'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'mmHg'	System	09 Aug 2020 01:08:20

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:58:51
User entered '78'	Janna Martinez (b) (4)	09 Aug 2020 01:08:20
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User entered 'mmHg'	System	09 Aug 2020 01:08:20

**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05



**US3062151**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05

**US3062151**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:04:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:23:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:14
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:08:24
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:23:07
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.'	(b) (4), (b) (6)	06 Sep 2020 13:28:44
canceled (Site from System).		
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 19:12:15
User entered '07 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:14
User entered empty.	(b) (4)	
	Janna Martinez (b) (4)	09 Aug 2020 01:08:24
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:04:29**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01

US3062151

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:04:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01
	(b) (4)	

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:04:29**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:04:29**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:09:01
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:09:01
	(b) (4)	



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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:04:29**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:25:44
User closed query 'Per source date of post-menopausal 01-Jan-2005. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 19:25:39
User closed query 'Per CDM: The date of last menstruation differs from the date recorded in Medical History form. Please review and update the Medical History form accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:35:57
Query 'Per CDM: The date of last menstruation differs from the date recorded in Medical History form. Please review and update the Medical History form accordingly. Thank you.' answered with 'postmenopausal post last menses' (Site from DM).	marissa Mueller (b) (4)	14 Sep 2020 19:09:26
User opened query 'Per CDM: The date of last menstruation differs from the date recorded in Medical History form. Please review and update the Medical History form accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:34:02
Query 'Per source date of post-menopausal 01-Jan-2005. Please verify and update if needed. ' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	10 Sep 2020 01:07:16
User entered '01 Jan 2005' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 01:07:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User opened query 'Per source date of post-menopausal 01-Jan-2005. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 16:20:23
User entered 'UN UNK 2005'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01
	(b) (4)	

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:04:29**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:20:26
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	09 Aug 2020 01:09:31
User entered '1' reason for change: Data Entry Error	Janna Martinez (b) (4)	09 Aug 2020 01:09:31
	(b) (4)	
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	09 Aug 2020 01:09:24
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

**US3062151**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:04:29**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:19:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:19:07
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:09:24
	(b) (4)	



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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:27:29
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:39
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:27:29
User entered '7 Aug 2020'	Janna Martinez (b) (4)	07 Aug 2020 18:04:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

[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 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:27:29
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	07 Aug 2020 18:04:39
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'VISIT1'	System	07 Aug 2020 18:04:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:53:48
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:53:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 17:29:11
User entered '185226' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
User closed query 'Subject with MH of COPD-please enter PD for misrandomization as subject should have been in AT RISK strata.' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 20:46:16
Query 'Subject with MH of COPD-please enter PD for misrandomization as subject should have been in AT RISK strata.' answered with 'did not deviate. Subject was stratified as high risk' (Site from CRA).	marissa Mueller (b) (4)	18 Dec 2020 16:07:46
User opened query 'Subject with MH of COPD-please enter PD for misrandomization as subject should have been in AT RISK strata.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:35:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:29

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 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:34:36
User closed query 'COPD is still listed in MH section in screening tab-please reconcile' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:34:31
Query 'COPD is still listed in MH section in screening tab-please reconcile' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	17 Dec 2020 21:29:10
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	17 Dec 2020 21:28:59
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	17 Dec 2020 21:28:59
	(b) (4)	
User opened query 'COPD is still listed in MH section in screening tab-please reconcile' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:53:47
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:26:14
User closed query 'Per source this has been updated as 'No.' Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 19:26:11
Query 'Per source this has been updated as 'No.' Please verify and update as needed. ' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	10 Sep 2020 01:04:56
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	10 Sep 2020 01:04:52
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:11
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User opened query 'Per source this has been updated as 'No.' Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 16:29:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:30
	(b) (4)	



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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:29**

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 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered 'No (N)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:30

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:29**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered 'No (N)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:30
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:29**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered 'No (N)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:30
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:29**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:07
User entered 'No (N)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:30
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:04:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '163.0' cm	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '71.6' kg	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:04:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '163.0' cm	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '71.6' kg	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '11:45'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered '07 Aug 2020 11:45'	System	09 Aug 2020 01:11:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:20:39
User closed query 'Per source temperature is 98.0 F. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:04:45
Query 'Per source temperature is 98.0 F. Please verify and update if needed. ' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	14 Sep 2020 19:10:53
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
	marissa Mueller (b) (4)	14 Sep 2020 19:10:47
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:32:06
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User opened query 'Per source temperature is 98.0 F. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 16:22:42
User entered '96.8' F	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '59'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'bpm'	System	09 Aug 2020 01:11:02

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '14'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'breaths/min'	System	09 Aug 2020 01:11:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '129'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'mmHg'	System	09 Aug 2020 01:11:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '78'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'mmHg'	System	09 Aug 2020 01:11:02



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '163.0' cm	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:04:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:03
User entered '71.6' kg	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 07:34:32
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	09 Aug 2020 01:11:26
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	09 Aug 2020 01:11:02
User entered '13:25'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered '07 Aug 2020 13:25'	System	09 Aug 2020 01:11:02

US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:21:25
User closed query 'Per source temperature is 96.8 F. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 21:04:55
Query 'Per source temperature is 96.8 F. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	14 Sep 2020 19:11:32
User entered '96.8' F reason for change: Data Entry Error	(b) (4)	
	marissa Mueller (b) (4)	14 Sep 2020 19:11:27
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:32:01
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User opened query 'Per source temperature is 96.8 F. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 16:31:43
User entered '98.0' F	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	



US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '66'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'bpm'	System	09 Aug 2020 01:11:02

US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '16'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'breaths/min'	System	09 Aug 2020 01:11:02

US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '118'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'mmHg'	System	09 Aug 2020 01:11:02



US3062151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:31:52
User entered '60'	Janna Martinez (b) (4)	09 Aug 2020 01:11:02
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'mmHg'	System	09 Aug 2020 01:11:02

US3062151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:23:14
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:22
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:37
	(b) (4)	

US3062151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:23:14
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:59:22
	(b) (4)	
User entered '7 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:11:37
	(b) (4)	

US3062151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered 'Yes (Y)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered empty.	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

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 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered empty.	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:06:52



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered '7 Aug 2020'	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered '12:51'	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered '7 Aug 2020 12:51'	System	07 Aug 2020 18:06:52

US3062151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered 'Left Arm (LEFT ARM)'	Janna Martinez (b) (4)	07 Aug 2020 18:06:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:30:23
User entered 'ONCE'	System	07 Aug 2020 18:06:52

US3062151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:06:52

US3062151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:00
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:11:53
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:00
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:11:53
	(b) (4)	



**US3062151**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:00
User entered '12:05'	Janna Martinez (b) (4)	09 Aug 2020 01:11:53
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered '07 Aug 2020 12:05'	System	09 Aug 2020 01:11:53

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:04:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:05
User entered '07 Aug 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:05
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:05
User entered '12:09'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered '07 Aug 2020 12:09'	System	09 Aug 2020 01:12:06

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	



US3062151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:04:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:05
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:28:05
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:12:06
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered empty.	System	09 Aug 2020 01:12:06

US3062151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:32:37
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:01:52
	(b) (4)	

**US3062151**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'I'	System	09 Aug 2020 01:01:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:28:42', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '50210b52-7f60-42f6-843a-7540c77812d3' User entered 'Yes (Y)'	System	07 Aug 2020 18:29:13
	System	07 Aug 2020 18:29:13

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:28:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '50210b52-7f60-42f6-843a-7540c77812d3' User entered '96.8'	System	07 Aug 2020 18:29:13
	System	07 Aug 2020 18:29:13



US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:28:35', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '50210b52-7f60-42f6-843a-7540c77812d3' User entered 'No (N)'	System	07 Aug 2020 18:29:13
	System	07 Aug 2020 18:29:13

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:29:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '50210b52-7f60-42f6-843a-7540c77812d3' User entered '07 Aug 2020 13:29'	System	07 Aug 2020 18:29:13
	System	07 Aug 2020 18:29:13

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 15:41'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17



US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 16:36'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 2'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:25:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3dd72980-f1f9-40a4-bda4-e6ac045199b0' User entered 'Yes (Y)'	System	08 Aug 2020 20:26:07
	System	08 Aug 2020 20:26:07

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:25:45', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3dd72980-f1f9-40a4-bda4-e6ac045199b0' User entered '97.8'	System	08 Aug 2020 20:26:07
	System	08 Aug 2020 20:26:07



US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:25:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3dd72980-f1f9-40a4-bda4-e6ac045199b0'	System	08 Aug 2020 20:26:07
User entered 'No (N)'	System	08 Aug 2020 20:26:07

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:04', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3dd72980-f1f9-40a4-bda4-e6ac045199b0' User entered '08 Aug 2020 15:26'	System	08 Aug 2020 20:26:07
	System	08 Aug 2020 20:26:07

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 3'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:04:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0716bd8b-536b-4b70-9d27-c20e0c19e26e' User entered 'Yes (Y)'	System	09 Aug 2020 19:05:10
	System	09 Aug 2020 19:05:10

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:04:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0716bd8b-536b-4b70-9d27-c20e0c19e26e' User entered '98.3'	System	09 Aug 2020 19:05:10
	System	09 Aug 2020 19:05:10

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0716bd8b-536b-4b70-9d27-c20e0c19e26e' User entered 'No (N)'	System	09 Aug 2020 19:05:10
	System	09 Aug 2020 19:05:10



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0716bd8b-536b-4b70-9d27-c20e0c19e26e' User entered '09 Aug 2020 14:05'	System	09 Aug 2020 19:05:10
	System	09 Aug 2020 19:05:10

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 4'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:36:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b90d339c-5e88-4803-b283-9abc982e6768' User entered 'Yes (Y)'	System	10 Aug 2020 19:37:23
	System	10 Aug 2020 19:37:23

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b90d339c-5e88-4803-b283-9abc982e6768' User entered '98.2'	System	10 Aug 2020 19:37:23
	System	10 Aug 2020 19:37:23

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b90d339c-5e88-4803-b283-9abc982e6768'	System	10 Aug 2020 19:37:23
User entered 'No (N)'	System	10 Aug 2020 19:37:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b90d339c-5e88-4803-b283-9abc982e6768' User entered '10 Aug 2020 14:37'	System	10 Aug 2020 19:37:23
	System	10 Aug 2020 19:37:23



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 5'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:58:55', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4d4ed43b-d046-4ce1-a975-20b9eac3b63e' User entered 'Yes (Y)'	System	11 Aug 2020 18:59:28
	System	11 Aug 2020 18:59:28

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:10', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4d4ed43b-d046-4ce1-a975-20b9eac3b63e' User entered '98.2'	System	11 Aug 2020 18:59:28
	System	11 Aug 2020 18:59:28

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:14', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4d4ed43b-d046-4ce1-a975-20b9eac3b63e' User entered 'No (N)'	System	11 Aug 2020 18:59:28
	System	11 Aug 2020 18:59:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4d4ed43b-d046-4ce1-a975-20b9eac3b63e' User entered '11 Aug 2020 13:59'	System	11 Aug 2020 18:59:28
	System	11 Aug 2020 18:59:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 6'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a3461955-f118-4658-97f1-27286816b456' User entered 'Yes (Y)'	System	12 Aug 2020 18:58:35
	System	12 Aug 2020 18:58:35

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a3461955-f118-4658-97f1-27286816b456' User entered '98.2'	System	12 Aug 2020 18:58:35
	System	12 Aug 2020 18:58:35

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a3461955-f118-4658-97f1-27286816b456'	System	12 Aug 2020 18:58:35
User entered 'No (N)'	System	12 Aug 2020 18:58:35

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a3461955-f118-4658-97f1-27286816b456'	System	12 Aug 2020 18:58:35
User entered '12 Aug 2020 13:58'	System	12 Aug 2020 18:58:35

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 7'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:02:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fe829fd8-e8b5-4550-a836-8b0e6e715829' User entered 'Yes (Y)'	System	13 Aug 2020 19:03:05
	System	13 Aug 2020 19:03:05

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:02:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fe829fd8-e8b5-4550-a836-8b0e6e715829' User entered '98.3'	System	13 Aug 2020 19:03:05
	System	13 Aug 2020 19:03:05

US3062151

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:02:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fe829fd8-e8b5-4550-a836-8b0e6e715829'	System	13 Aug 2020 19:03:05
User entered 'No (N)'	System	13 Aug 2020 19:03:05

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fe829fd8-e8b5-4550-a836-8b0e6e715829' User entered '13 Aug 2020 14:03'	System	13 Aug 2020 19:03:05
	System	13 Aug 2020 19:03:05

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:29:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '102ff28d-f9eb-42ff-81dd-0ffe4f86403c'	System	07 Aug 2020 18:30:12
User entered 'None (1)'	System	07 Aug 2020 18:30:12

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:29:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '102ff28d-f9eb-42ff-81dd-0ffe4f86403c'	System	07 Aug 2020 18:30:12
User entered 'No (N)'	System	07 Aug 2020 18:30:12

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:29:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '102ff28d-f9eb-42ff-81dd-0ffe4f86403c'	System	07 Aug 2020 18:30:12
User entered 'No (N)'	System	07 Aug 2020 18:30:12

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:30:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '102ff28d-f9eb-42ff-81dd-0ffe4f86403c'	System	07 Aug 2020 18:30:12
User entered 'None (1)'	System	07 Aug 2020 18:30:12

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:30:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '102ff28d-f9eb-42ff-81dd-0ffe4f86403c'	System	07 Aug 2020 18:30:12
User entered '07 Aug 2020 13:30'	System	07 Aug 2020 18:30:12

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 15:41'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:06:52



US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 16:36'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 2'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bac0abc8-cccd-4ec3-8a53-fa5d7702f269'	System	08 Aug 2020 20:26:54
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 20:26:54

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bac0abc8-cccd-4ec3-8a53-fa5d7702f269'	System	08 Aug 2020 20:26:54
User entered 'No (N)'	System	08 Aug 2020 20:26:54

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bac0abc8-cccd-4ec3-8a53-fa5d7702f269'	System	08 Aug 2020 20:26:54
User entered 'No (N)'	System	08 Aug 2020 20:26:54

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:45', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bac0abc8-cccd-4ec3-8a53-fa5d7702f269'	System	08 Aug 2020 20:26:54
User entered 'None (1)'	System	08 Aug 2020 20:26:54

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:26:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bac0abc8-cccd-4ec3-8a53-fa5d7702f269'	System	08 Aug 2020 20:26:54
User entered '08 Aug 2020 15:26'	System	08 Aug 2020 20:26:54

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 3'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:15', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '86d7d163-380d-4cad-b06b-b2830225963e'	System	09 Aug 2020 19:05:37
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 19:05:37

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '86d7d163-380d-4cad-b06b-b2830225963e' User entered 'No (N)'	System	09 Aug 2020 19:05:37
	System	09 Aug 2020 19:05:37

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '86d7d163-380d-4cad-b06b-b2830225963e' User entered 'No (N)'	System	09 Aug 2020 19:05:37
	System	09 Aug 2020 19:05:37

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:29', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '86d7d163-380d-4cad-b06b-b2830225963e' User entered 'None (1)'	System	09 Aug 2020 19:05:37
	System	09 Aug 2020 19:05:37

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-09T14:05:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '86d7d163-380d-4cad-b06b-b2830225963e' User entered '09 Aug 2020 14:05'	System	09 Aug 2020 19:05:37
	System	09 Aug 2020 19:05:37

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 4'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e67a632-f633-486f-b6a7-168c46220c0d' User entered 'None (1)'	System	10 Aug 2020 19:37:49
	System	10 Aug 2020 19:37:49

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e67a632-f633-486f-b6a7-168c46220c0d' User entered 'No (N)'	System	10 Aug 2020 19:37:49
	System	10 Aug 2020 19:37:49

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e67a632-f633-486f-b6a7-168c46220c0d' User entered 'No (N)'	System	10 Aug 2020 19:37:49
	System	10 Aug 2020 19:37:49

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e67a632-f633-486f-b6a7-168c46220c0d' User entered 'None (1)'	System	10 Aug 2020 19:37:49
	System	10 Aug 2020 19:37:49

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e67a632-f633-486f-b6a7-168c46220c0d' User entered '10 Aug 2020 14:37'	System	10 Aug 2020 19:37:49
	System	10 Aug 2020 19:37:49

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 5'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:29', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f368eea7-ae28-498a-a7f2-6e087ef43c8e'	System	11 Aug 2020 18:59:46
User entered 'None (1)'	System	11 Aug 2020 18:59:46

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f368eea7-ae28-498a-a7f2-6e087ef43c8e'	System	11 Aug 2020 18:59:46
User entered 'No (N)'	System	11 Aug 2020 18:59:46

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f368eea7-ae28-498a-a7f2-6e087ef43c8e'	System	11 Aug 2020 18:59:46
User entered 'No (N)'	System	11 Aug 2020 18:59:46

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:41', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f368eea7-ae28-498a-a7f2-6e087ef43c8e'	System	11 Aug 2020 18:59:46
User entered 'None (1)'	System	11 Aug 2020 18:59:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f368eea7-ae28-498a-a7f2-6e087ef43c8e' User entered '11 Aug 2020 13:59'	System	11 Aug 2020 18:59:46
	System	11 Aug 2020 18:59:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 6'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0f625931-745f-4fda-8588-cd49af1a8568'	System	12 Aug 2020 18:58:50
User entered 'None (1)'	System	12 Aug 2020 18:58:50

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:39', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0f625931-745f-4fda-8588-cd49af1a8568'	System	12 Aug 2020 18:58:50
User entered 'No (N)'	System	12 Aug 2020 18:58:50

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0f625931-745f-4fda-8588-cd49af1a8568'	System	12 Aug 2020 18:58:50
User entered 'No (N)'	System	12 Aug 2020 18:58:50

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0f625931-745f-4fda-8588-cd49af1a8568'	System	12 Aug 2020 18:58:50
User entered 'None (1)'	System	12 Aug 2020 18:58:50

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0f625931-745f-4fda-8588-cd49af1a8568'	System	12 Aug 2020 18:58:50
User entered '12 Aug 2020 13:58'	System	12 Aug 2020 18:58:50

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 7'	System	07 Aug 2020 18:06:52

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4007720b-819f-4782-9877-d403593ad9fd' User entered 'None (1)'	System	13 Aug 2020 19:03:23
	System	13 Aug 2020 19:03:23

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:09', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4007720b-819f-4782-9877-d403593ad9fd' User entered 'No (N)'	System	13 Aug 2020 19:03:23
	System	13 Aug 2020 19:03:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4007720b-819f-4782-9877-d403593ad9fd' User entered 'No (N)'	System	13 Aug 2020 19:03:23
	System	13 Aug 2020 19:03:23

US3062151

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:17', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4007720b-819f-4782-9877-d403593ad9fd' User entered 'None (1)'	System	13 Aug 2020 19:03:23
	System	13 Aug 2020 19:03:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4007720b-819f-4782-9877-d403593ad9fd' User entered '13 Aug 2020 14:03'	System	13 Aug 2020 19:03:23
	System	13 Aug 2020 19:03:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:30:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:30:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:30:42', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:31:03', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:31:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:31:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered 'None (0)'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24



US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:31:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000'	System	07 Aug 2020 18:31:24
User entered 'No (N)'	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-07T13:31:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fef54d01-9f56-4e79-9567-9529f8979000' User entered '07 Aug 2020 13:31'	System	07 Aug 2020 18:31:24
	System	07 Aug 2020 18:31:24

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 15:41'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17



US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 21:34:17

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 21:34:17

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Aug 2020 16:36'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 2'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47' User entered 'None (0)'	System	08 Aug 2020 20:27:46
	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47'	System	08 Aug 2020 20:27:46
User entered 'No interference with activity (1)'	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47'	System	08 Aug 2020 20:27:46
User entered 'No interference with activity (1)'	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47'	System	08 Aug 2020 20:27:46
User entered 'No interference with activity (1)'	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47' User entered 'None (0)'	System	08 Aug 2020 20:27:46
	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47' User entered 'None (0)'	System	08 Aug 2020 20:27:46
	System	08 Aug 2020 20:27:46

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:38', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47'	System	08 Aug 2020 20:27:46
User entered 'No (N)'	System	08 Aug 2020 20:27:46

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-08T15:27:42', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b2692978-1f88-4589-97d3-e5680f3c9c47'	System	08 Aug 2020 20:27:46
User entered '08 Aug 2020 15:27'	System	08 Aug 2020 20:27:46



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 3'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:13:58', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'None (0)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'None (0)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'None (0)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c'	System	10 Aug 2020 14:14:28
User entered 'No interference with activity (1)'	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'None (0)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:16', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'None (0)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered 'No (N)'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T09:14:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '39006c10-8c56-4eb4-8394-5e3f6ac0911c' User entered '10 Aug 2020 09:14'	System	10 Aug 2020 14:14:28
	System	10 Aug 2020 14:14:28

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 4'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'None (0)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'None (0)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:37:59', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'None (0)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:38:04', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0'	System	10 Aug 2020 19:38:23
User entered 'No interference with activity (1)'	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:38:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'None (0)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:38:09', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'None (0)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

US3062151

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:38:14', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered 'No (N)'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-10T14:38:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '912d6d3f-1e9c-449d-b945-6ced5e3a7ce0' User entered '10 Aug 2020 14:38'	System	10 Aug 2020 19:38:23
	System	10 Aug 2020 19:38:23

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 5'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered 'None (0)'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered 'None (0)'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered 'None (0)'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T13:59:59', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234'	System	11 Aug 2020 19:00:18
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T14:00:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered 'None (0)'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T14:00:04', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered 'None (0)'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T14:00:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234'	System	11 Aug 2020 19:00:18
User entered 'No (N)'	System	11 Aug 2020 19:00:18



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-11T14:00:14', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '17c6a9b3-b229-428c-80d4-5fa9cdc25234' User entered '11 Aug 2020 14:00'	System	11 Aug 2020 19:00:18
	System	11 Aug 2020 19:00:18

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 6'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:58:58', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:08', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:10', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered 'None (0)'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:17', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86'	System	12 Aug 2020 18:59:21
User entered 'No (N)'	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-12T13:59:19', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4f253590-58bd-42d9-835a-1eb57d5cbb86' User entered '12 Aug 2020 13:59'	System	12 Aug 2020 18:59:21
	System	12 Aug 2020 18:59:21

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 7'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:30', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:33', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered 'None (0)'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7'	System	13 Aug 2020 19:03:56
User entered 'No (N)'	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-08-13T14:03:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '072e0697-9a66-49b2-a14b-fc2d84672aa7' User entered '13 Aug 2020 14:03'	System	13 Aug 2020 19:03:56
	System	13 Aug 2020 19:03:56

**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:06:52



**US3062151**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:18
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 19:42:17
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:18
User entered '15 Aug 2020'	Janna Martinez (b) (4)	15 Aug 2020 19:42:17
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:18
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	15 Aug 2020 19:42:17
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:18
User entered empty.	Janna Martinez (b) (4)	15 Aug 2020 19:42:17
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:23
User entered 'Yes (Y)'	Janna Martinez (b) (4)	15 Aug 2020 19:42:04
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'I'	System	15 Aug 2020 19:42:04

US3062151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:29

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:45
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	26 Aug 2020 16:25:28
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	26 Aug 2020 16:25:24
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 16:25:24



**US3062151**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:45
User entered '22 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 16:25:24
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:45
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Janna Martinez (b) (4)	26 Aug 2020 16:25:28
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 16:25:24
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:45
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 16:25:24
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:34:49
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 16:25:12
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:03:51
User entered 'I'	System	26 Aug 2020 16:25:12

**US3062151**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:13
User entered 'Yes (Y)'	marissa Mueller (b) (4)	31 Aug 2020 15:06:15
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:13
User entered '30 Aug 2020'	marissa Mueller (b) (4)	31 Aug 2020 15:06:15
	(b) (4)	

US3062151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:13
User entered 'Contact Made (CONTACT MADE)'	marissa Mueller (b) (4)	31 Aug 2020 15:06:15
	(b) (4)	



**US3062151**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:13
User entered empty.	marissa Mueller (b) (4)	31 Aug 2020 15:06:15
	(b) (4)	

US3062151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:16
User entered 'Yes (Y)'	marissa Mueller (b) (4)	31 Aug 2020 15:06:19
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:05:02
User entered 'I'	System	31 Aug 2020 15:06:19

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:20:29
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 19:12:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:20:29
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 19:12:15
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:20:29
User entered 'Clinic (Clinic)'	Brianna Burton (b) (4)	04 Sep 2020 19:12:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'VISIT2'	System	04 Sep 2020 19:12:15

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	



US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '13:12'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '04 Sep 2020 13:12'	System	04 Sep 2020 22:26:43

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '98.2' F	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '77'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	



**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'bpm'	System	04 Sep 2020 22:26:43

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '14'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'breaths/min'	System	04 Sep 2020 22:26:43

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '107'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	04 Sep 2020 22:26:43

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '72'	Janna Martinez (b) (4)	04 Sep 2020 22:26:43
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	04 Sep 2020 22:26:43

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	



US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '14:39'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '04 Sep 2020 14:39'	System	04 Sep 2020 22:27:15

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '98.3' F	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '74'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	



**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'bpm'	System	04 Sep 2020 22:27:15

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '14'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'breaths/min'	System	04 Sep 2020 22:27:15

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User entered '119'	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	04 Sep 2020 22:27:15

US3062151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:21:57
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:27:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 22:27:23
User entered '78' reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 22:27:23
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:27:15
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:27:15
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	04 Sep 2020 22:27:23
User entered empty.	System	04 Sep 2020 22:27:15

US3062151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:25:20
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:32:39
	(b) (4)	



US3062151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:25:20
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 22:32:46
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	04 Sep 2020 22:32:46
User entered '04 Sep 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 22:32:46
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 22:32:39
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	04 Sep 2020 22:32:39
User entered '04 Aug 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:32:39
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 19:12:38

US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered '14:08'	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '4 Sep 2020 14:08'	System	04 Sep 2020 19:12:38



US3062151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:29

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered 'Left Arm (LEFT ARM)'	Brianna Burton (b) (4)	04 Sep 2020 19:12:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:27
User entered 'ONCE'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:29**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:44
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:10
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:44
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:33:10
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:44
User entered '13:20' reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 22:33:48
	(b) (4)	
User entered '13:18'	Janna Martinez (b) (4)	04 Sep 2020 22:33:10
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '04 Sep 2020 13:20'	System	04 Sep 2020 22:33:48
User entered '04 Sep 2020 13:18'	System	04 Sep 2020 22:33:10

US3062151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:04:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	



**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered '13:18'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '04 Sep 2020 13:18'	System	04 Sep 2020 22:33:38

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:26:59
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:33:38
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered empty.	System	04 Sep 2020 22:33:38



US3062151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:27:12
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:33:52
	(b) (4)	

**US3062151**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	04 Sep 2020 22:33:52

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:39:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'd2e626d4-9c81-4d3d-bb1e-5cab6362e527'	System	04 Sep 2020 19:41:12
User entered 'Yes (Y)'	System	04 Sep 2020 19:41:12

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:40:30', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'd2e626d4-9c81-4d3d-bb1e-5cab6362e527' User entered '98.3'	System	04 Sep 2020 19:41:12
	System	04 Sep 2020 19:41:12

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:40:41', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'd2e626d4-9c81-4d3d-bb1e-5cab6362e527'	System	04 Sep 2020 19:41:12
User entered 'No (N)'	System	04 Sep 2020 19:41:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:08', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'd2e626d4-9c81-4d3d-bb1e-5cab6362e527'	System	04 Sep 2020 19:41:12
User entered '04 Sep 2020 14:41'	System	04 Sep 2020 19:41:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 14:28'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 16:58'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:01:19', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bfbecf20-f405-4cdd-bd21-6145368ccd83'	System	05 Sep 2020 00:01:47
User entered 'Yes (Y)'	System	05 Sep 2020 00:01:47

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:01:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bfbecf20-f405-4cdd-bd21-6145368ccd83'	System	05 Sep 2020 00:01:47
User entered '98.2'	System	05 Sep 2020 00:01:47

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:01:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bfbecf20-f405-4cdd-bd21-6145368ccd83'	System	05 Sep 2020 00:01:47
User entered 'No (N)'	System	05 Sep 2020 00:01:47

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:01:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'bfbecf20-f405-4cdd-bd21-6145368ccd83'	System	05 Sep 2020 00:01:47
User entered '04 Sep 2020 19:01'	System	05 Sep 2020 00:01:47

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 2'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:51:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4697cd84-4764-4d23-8aca-51c69cf6f850'	System	05 Sep 2020 23:52:35
User entered 'Yes (Y)'	System	05 Sep 2020 23:52:35

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:52:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4697cd84-4764-4d23-8aca-51c69cf6f850' User entered '100.3'	System	05 Sep 2020 23:52:35
	System	05 Sep 2020 23:52:35

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:52:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4697cd84-4764-4d23-8aca-51c69cf6f850'	System	05 Sep 2020 23:52:35
User entered 'No (N)'	System	05 Sep 2020 23:52:35

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:52:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4697cd84-4764-4d23-8aca-51c69cf6f850'	System	05 Sep 2020 23:52:35
User entered '05 Sep 2020 18:52'	System	05 Sep 2020 23:52:35

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 3'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:12', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'abc4223f-3463-4896-ba3d-bb9517115d1d' User entered 'Yes (Y)'	System	06 Sep 2020 23:54:36
	System	06 Sep 2020 23:54:36

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'abc4223f-3463-4896-ba3d-bb9517115d1d' User entered '97.7'	System	06 Sep 2020 23:54:36
	System	06 Sep 2020 23:54:36

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:29', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'abc4223f-3463-4896-ba3d-bb9517115d1d' User entered 'No (N)'	System	06 Sep 2020 23:54:36
	System	06 Sep 2020 23:54:36

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'abc4223f-3463-4896-ba3d-bb9517115d1d' User entered '06 Sep 2020 18:54'	System	06 Sep 2020 23:54:36
	System	06 Sep 2020 23:54:36

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 4'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:51:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9f6b562b-5b33-4157-9537-a30654a6f6aa' User entered 'Yes (Y)'	System	07 Sep 2020 23:52:03
	System	07 Sep 2020 23:52:03



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:51:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9f6b562b-5b33-4157-9537-a30654a6f6aa' User entered '97.8'	System	07 Sep 2020 23:52:03
	System	07 Sep 2020 23:52:03

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:51:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9f6b562b-5b33-4157-9537-a30654a6f6aa'	System	07 Sep 2020 23:52:03
User entered 'No (N)'	System	07 Sep 2020 23:52:03

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9f6b562b-5b33-4157-9537-a30654a6f6aa' User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:03
	System	07 Sep 2020 23:52:03

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 5'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'beab52f6-00e6-492d-9903-4e1564c83883' User entered 'Yes (Y)'	System	08 Sep 2020 23:59:45
	System	08 Sep 2020 23:59:45

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'beab52f6-00e6-492d-9903-4e1564c83883' User entered '98.1'	System	08 Sep 2020 23:59:45
	System	08 Sep 2020 23:59:45



US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'beab52f6-00e6-492d-9903-4e1564c83883' User entered 'No (N)'	System	08 Sep 2020 23:59:45
	System	08 Sep 2020 23:59:45

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'beab52f6-00e6-492d-9903-4e1564c83883' User entered '08 Sep 2020 18:59'	System	08 Sep 2020 23:59:45
	System	08 Sep 2020 23:59:45

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 6'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:10', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'ef13960d-abfc-41bf-839b-8dc40c58493c' User entered 'Yes (Y)'	System	10 Sep 2020 00:08:26
	System	10 Sep 2020 00:08:26

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:16', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'ef13960d-abfc-41bf-839b-8dc40c58493c' User entered '98.3'	System	10 Sep 2020 00:08:26
	System	10 Sep 2020 00:08:26

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'ef13960d-abfc-41bf-839b-8dc40c58493c'	System	10 Sep 2020 00:08:26
User entered 'No (N)'	System	10 Sep 2020 00:08:26



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'ef13960d-abfc-41bf-839b-8dc40c58493c' User entered '09 Sep 2020 19:08'	System	10 Sep 2020 00:08:26
	System	10 Sep 2020 00:08:26

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 7'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9094bb48-4038-496d-965e-ce5925aba385' User entered 'Yes (Y)'	System	11 Sep 2020 00:03:32
	System	11 Sep 2020 00:03:32

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:19', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9094bb48-4038-496d-965e-ce5925aba385' User entered '97.0'	System	11 Sep 2020 00:03:32
	System	11 Sep 2020 00:03:32

US3062151

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9094bb48-4038-496d-965e-ce5925aba385'	System	11 Sep 2020 00:03:32
User entered 'No (N)'	System	11 Sep 2020 00:03:32

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9094bb48-4038-496d-965e-ce5925aba385' User entered '10 Sep 2020 19:03'	System	11 Sep 2020 00:03:32
	System	11 Sep 2020 00:03:32



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:18', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '96bd0ebd-1b62-4691-9f4d-6591c361886e' User entered 'None (1)'	System	04 Sep 2020 19:41:40
	System	04 Sep 2020 19:41:40

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '96bd0ebd-1b62-4691-9f4d-6591c361886e' User entered 'No (N)'	System	04 Sep 2020 19:41:40
	System	04 Sep 2020 19:41:40

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '96bd0ebd-1b62-4691-9f4d-6591c361886e' User entered 'No (N)'	System	04 Sep 2020 19:41:40
	System	04 Sep 2020 19:41:40

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '96bd0ebd-1b62-4691-9f4d-6591c361886e' User entered 'None (1)'	System	04 Sep 2020 19:41:40
	System	04 Sep 2020 19:41:40

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '96bd0ebd-1b62-4691-9f4d-6591c361886e' User entered '04 Sep 2020 14:41'	System	04 Sep 2020 19:41:40
	System	04 Sep 2020 19:41:40



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 14:28'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 16:58'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:01:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '8bbfab75-f0fb-4a00-8425-087f26f0f601'	System	05 Sep 2020 00:02:39
User entered 'None (1)'	System	05 Sep 2020 00:02:39

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:22', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '8bbfab75-f0fb-4a00-8425-087f26f0f601' User entered 'No (N)'	System	05 Sep 2020 00:02:39
	System	05 Sep 2020 00:02:39

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '8bbfab75-f0fb-4a00-8425-087f26f0f601' User entered 'No (N)'	System	05 Sep 2020 00:02:39
	System	05 Sep 2020 00:02:39

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '8bbfab75-f0fb-4a00-8425-087f26f0f601' User entered 'None (1)'	System	05 Sep 2020 00:02:39
	System	05 Sep 2020 00:02:39

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '8bbfab75-f0fb-4a00-8425-087f26f0f601' User entered '04 Sep 2020 19:02'	System	05 Sep 2020 00:02:39
	System	05 Sep 2020 00:02:39



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 2'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:52:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'db0618c7-47e2-4586-b015-fca3a32737d8'	System	05 Sep 2020 23:53:58
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:53:58

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:52:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'db0618c7-47e2-4586-b015-fca3a32737d8' User entered 'No (N)'	System	05 Sep 2020 23:53:58
	System	05 Sep 2020 23:53:58

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:53:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'db0618c7-47e2-4586-b015-fca3a32737d8' User entered 'No (N)'	System	05 Sep 2020 23:53:58
	System	05 Sep 2020 23:53:58

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:53:44', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'db0618c7-47e2-4586-b015-fca3a32737d8' User entered 'None (1)'	System	05 Sep 2020 23:53:58
	System	05 Sep 2020 23:53:58

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:53:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'db0618c7-47e2-4586-b015-fca3a32737d8' User entered '05 Sep 2020 18:53'	System	05 Sep 2020 23:53:58
	System	05 Sep 2020 23:53:58



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 3'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:44', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b625f32a-2162-4769-ba00-d87111a8bd91'	System	06 Sep 2020 23:55:01
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:55:01

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:48', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b625f32a-2162-4769-ba00-d87111a8bd91' User entered 'No (N)'	System	06 Sep 2020 23:55:01
	System	06 Sep 2020 23:55:01

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:52', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b625f32a-2162-4769-ba00-d87111a8bd91' User entered 'No (N)'	System	06 Sep 2020 23:55:01
	System	06 Sep 2020 23:55:01

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:54:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b625f32a-2162-4769-ba00-d87111a8bd91' User entered 'None (1)'	System	06 Sep 2020 23:55:01
	System	06 Sep 2020 23:55:01

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b625f32a-2162-4769-ba00-d87111a8bd91' User entered '06 Sep 2020 18:55'	System	06 Sep 2020 23:55:01
	System	06 Sep 2020 23:55:01



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 4'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc365a59-5710-4f03-87fe-8254861e2cfd' User entered 'None (1)'	System	07 Sep 2020 23:52:26
	System	07 Sep 2020 23:52:26

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc365a59-5710-4f03-87fe-8254861e2cfd' User entered 'No (N)'	System	07 Sep 2020 23:52:26
	System	07 Sep 2020 23:52:26

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:15', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc365a59-5710-4f03-87fe-8254861e2cfd' User entered 'No (N)'	System	07 Sep 2020 23:52:26
	System	07 Sep 2020 23:52:26

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc365a59-5710-4f03-87fe-8254861e2cfd' User entered 'None (1)'	System	07 Sep 2020 23:52:26
	System	07 Sep 2020 23:52:26

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc365a59-5710-4f03-87fe-8254861e2cfd' User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:26
	System	07 Sep 2020 23:52:26



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 5'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'cbea96b2-ca46-4097-a29b-cd4237ed20c0' User entered 'None (1)'	System	09 Sep 2020 00:00:09
	System	09 Sep 2020 00:00:09

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'cbea96b2-ca46-4097-a29b-cd4237ed20c0'	System	09 Sep 2020 00:00:09
User entered 'No (N)'	System	09 Sep 2020 00:00:09

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T18:59:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'cbea96b2-ca46-4097-a29b-cd4237ed20c0' User entered 'No (N)'	System	09 Sep 2020 00:00:09
	System	09 Sep 2020 00:00:09

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'cbea96b2-ca46-4097-a29b-cd4237ed20c0'	System	09 Sep 2020 00:00:09
User entered 'None (1)'	System	09 Sep 2020 00:00:09

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:03', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'cbea96b2-ca46-4097-a29b-cd4237ed20c0' User entered '08 Sep 2020 19:00'	System	09 Sep 2020 00:00:09
	System	09 Sep 2020 00:00:09



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 6'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:30', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '73953dc9-8210-4288-8b45-8296aba5312a' User entered 'None (1)'	System	10 Sep 2020 00:08:46
	System	10 Sep 2020 00:08:46

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:33', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '73953dc9-8210-4288-8b45-8296aba5312a'	System	10 Sep 2020 00:08:46
User entered 'No (N)'	System	10 Sep 2020 00:08:46

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '73953dc9-8210-4288-8b45-8296aba5312a'	System	10 Sep 2020 00:08:46
User entered 'No (N)'	System	10 Sep 2020 00:08:46

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '73953dc9-8210-4288-8b45-8296aba5312a' User entered 'None (1)'	System	10 Sep 2020 00:08:46
	System	10 Sep 2020 00:08:46

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:44', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '73953dc9-8210-4288-8b45-8296aba5312a' User entered '09 Sep 2020 19:08'	System	10 Sep 2020 00:08:46
	System	10 Sep 2020 00:08:46



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 7'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:33', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '79e31d4e-7f49-441b-bda7-645ceacf2999'	System	11 Sep 2020 00:03:49
User entered 'None (1)'	System	11 Sep 2020 00:03:49

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '79e31d4e-7f49-441b-bda7-645ceacf2999'	System	11 Sep 2020 00:03:49
User entered 'No (N)'	System	11 Sep 2020 00:03:49

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:39', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '79e31d4e-7f49-441b-bda7-645ceacf2999'	System	11 Sep 2020 00:03:49
User entered 'No (N)'	System	11 Sep 2020 00:03:49

US3062151

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '79e31d4e-7f49-441b-bda7-645ceacf2999'	System	11 Sep 2020 00:03:49
User entered 'None (1)'	System	11 Sep 2020 00:03:49

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '79e31d4e-7f49-441b-bda7-645ceacf2999'	System	11 Sep 2020 00:03:49
User entered '10 Sep 2020 19:03'	System	11 Sep 2020 00:03:49



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:39', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:41:55', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:42:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'None (0)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:42:11', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered 'No (N)'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T14:42:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8f657ce-1ec0-4e29-8f90-db8d679d417f' User entered '04 Sep 2020 14:42'	System	04 Sep 2020 19:42:17
	System	04 Sep 2020 19:42:17

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 14:28'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 16:58'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:40', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:02:55', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'None (0)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:03:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered 'No (N)'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-04T19:03:05', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c2a55b7f-a2a9-4a71-97f2-d7603b97a9dd' User entered '04 Sep 2020 19:03'	System	05 Sep 2020 00:03:08
	System	05 Sep 2020 00:03:08

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '04 Sep 2020 17:53'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 2'	System	04 Sep 2020 19:12:38

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User closed query 'please verify in source documentation of PI discretion of symptomology' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:02:27
Query 'please verify in source documentation of PI discretion of symptomology' answered with 'see MTF' (Site from CRA).	marissa Mueller (b) (4)	21 Oct 2020 21:58:01
User opened query 'please verify in source documentation of PI discretion of symptomology' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:00:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:04', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8'	System	05 Sep 2020 23:54:51
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:12', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8'	System	05 Sep 2020 23:54:51
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8'	System	05 Sep 2020 23:54:51
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8'	System	05 Sep 2020 23:54:51
User entered 'Some interference with activity (2)'	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8' User entered 'None (0)'	System	05 Sep 2020 23:54:51
	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8' User entered 'None (0)'	System	05 Sep 2020 23:54:51
	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:42', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8' User entered 'No (N)'	System	05 Sep 2020 23:54:51
	System	05 Sep 2020 23:54:51



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-05T18:54:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5493c565-78c3-4576-bdf6-71416df1e2d8' User entered '05 Sep 2020 18:54'	System	05 Sep 2020 23:54:51
	System	05 Sep 2020 23:54:51

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 3'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered 'None (0)'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:12', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a'	System	06 Sep 2020 23:55:41
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:18', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a'	System	06 Sep 2020 23:55:41
User entered 'Some interference with activity (2)'	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered 'Some interference with activity (2)'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered 'None (0)'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:30', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered 'None (0)'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:35', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered 'No (N)'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-06T18:55:38', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b45a3903-bc83-472b-8333-1d281255f69a' User entered '06 Sep 2020 18:55'	System	06 Sep 2020 23:55:41
	System	06 Sep 2020 23:55:41

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 4'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710' User entered 'None (0)'	System	07 Sep 2020 23:52:57
	System	07 Sep 2020 23:52:57



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:35', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710'	System	07 Sep 2020 23:52:57
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:39', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710'	System	07 Sep 2020 23:52:57
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:42', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710'	System	07 Sep 2020 23:52:57
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:45', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710' User entered 'None (0)'	System	07 Sep 2020 23:52:57
	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:48', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710' User entered 'None (0)'	System	07 Sep 2020 23:52:57
	System	07 Sep 2020 23:52:57

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710' User entered 'No (N)'	System	07 Sep 2020 23:52:57
	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-07T18:52:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '15524377-ef44-465e-81fe-6eb1a7de9710' User entered '07 Sep 2020 18:52'	System	07 Sep 2020 23:52:57
	System	07 Sep 2020 23:52:57

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 5'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered 'None (0)'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765'	System	09 Sep 2020 00:00:43
User entered 'No interference with activity (1)'	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765'	System	09 Sep 2020 00:00:43
User entered 'No interference with activity (1)'	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:25', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered 'No interference with activity (1)'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:28', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered 'None (0)'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:30', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered 'None (0)'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered 'No (N)'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-08T19:00:39', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6246b6a5-0066-446f-8795-ea6486179765' User entered '08 Sep 2020 19:00'	System	09 Sep 2020 00:00:43
	System	09 Sep 2020 00:00:43

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 6'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:48', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:08:58', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:09:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'None (0)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

US3062151

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:29

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:09:06', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered 'No (N)'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-09T19:09:08', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '239800d0-2e5e-49e3-876f-f3c048dd1b9d' User entered '09 Sep 2020 19:09'	System	10 Sep 2020 00:09:12
	System	10 Sep 2020 00:09:12

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	04 Sep 2020 19:12:38
User entered 'Day 7'	System	04 Sep 2020 19:12:38



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:52', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:03:59', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:04:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:04:08', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered 'None (0)'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

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 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:04:16', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5'	System	11 Sep 2020 00:04:21
User entered 'No (N)'	System	11 Sep 2020 00:04:21

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-09-10T19:04:18', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'b66819d3-7b02-4fa7-8a41-634f5eb3eca5' User entered '10 Sep 2020 19:04'	System	11 Sep 2020 00:04:21
	System	11 Sep 2020 00:04:21



**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:12:38

**US3062151**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:35:34
User entered 'Yes (Y)'	Colton King (b) (4)	11 Sep 2020 21:53:50
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:35:34
User entered '11 Sep 2020'	Colton King (b) (4)	11 Sep 2020 21:53:50
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:35:34
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	11 Sep 2020 21:53:50
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:35:34
User entered empty.	Colton King (b) (4)	11 Sep 2020 21:53:50
	(b) (4)	

US3062151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:37:37
User entered 'Yes (Y)'	Colton King (b) (4)	11 Sep 2020 21:53:35
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	11 Sep 2020 21:53:35



**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:38:14
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 19:33:04
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:38:14
User entered '18 Sep 2020'	Colton King (b) (4)	25 Sep 2020 19:33:04
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:38:14
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	25 Sep 2020 19:33:04
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:38:14
User entered empty.	Colton King (b) (4)	25 Sep 2020 19:33:04
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:38:36
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 19:33:08
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	25 Sep 2020 19:33:08

**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:39:41
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 19:33:53
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:39:41
User entered '25 Sep 2020'	Colton King (b) (4)	25 Sep 2020 19:33:53
	(b) (4)	



**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:39:41
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	25 Sep 2020 19:33:53
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:39:41
User entered empty.	Colton King (b) (4)	25 Sep 2020 19:33:53
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 14:40:56
User entered 'Yes (Y)'	Colton King (b) (4)	25 Sep 2020 19:34:01
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	25 Sep 2020 19:34:01

**US3062151**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:28:30
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:40:38
	(b) (4)	

**US3062151**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:28:30
User entered '02 Oct 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:40:38
	(b) (4)	

US3062151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:28:30
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	02 Oct 2020 21:40:38
	(b) (4)	

**US3062151**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'VISIT3'	System	02 Oct 2020 21:40:38



US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '02 Oct 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '10:45'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '02 Oct 2020 10:45'	System	02 Oct 2020 21:41:45

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '98.6' F	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '76'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	



**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'bpm'	System	02 Oct 2020 21:41:45

US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '16'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'breaths/min'	System	02 Oct 2020 21:41:45

US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '104'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	02 Oct 2020 21:41:45

US3062151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:39
User entered '66'	Janna Martinez (b) (4)	02 Oct 2020 21:41:45
	(b) (4)	

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'mmHg'	System	02 Oct 2020 21:41:45

**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15



**US3062151**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15

US3062151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:49
User entered 'No (N)'	Janna Martinez (b) (4)	02 Oct 2020 21:41:51
	(b) (4)	

US3062151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:49
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:41:51
	(b) (4)	

**US3062151**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:31:03
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:42:06
	(b) (4)	

**US3062151**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

**Collection date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:31:03
User entered '02 Oct 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:42:06
	(b) (4)	

**US3062151**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:31:03
User entered '10:56'	Janna Martinez (b) (4)	02 Oct 2020 21:42:06
	(b) (4)	

**US3062151**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered '02 Oct 2020 10:56'	System	02 Oct 2020 21:42:06

US3062151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:34:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:31:11
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:44:59
	(b) (4)	



**US3062151**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	02 Oct 2020 21:44:59

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 64'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-08T07:38:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8205232-4f6b-4a74-b7fc-99bff3d75104'	System	08 Oct 2020 12:38:47
User entered 'No (N)'	System	08 Oct 2020 12:38:47

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-08T07:38:35', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8205232-4f6b-4a74-b7fc-99bff3d75104'	System	08 Oct 2020 12:38:47
User entered 'No (N)'	System	08 Oct 2020 12:38:47

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-08T07:38:45', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'e8205232-4f6b-4a74-b7fc-99bff3d75104' User entered '08 Oct 2020 07:38:45'	System	08 Oct 2020 12:38:47
	System	08 Oct 2020 12:38:47

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 71'	System	07 Aug 2020 18:06:52



**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-14T04:48:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4c6fecdl-dad1-4e3f-84e6-b12eac2c18f6'	System	14 Oct 2020 09:49:07
User entered 'No (N)'	System	14 Oct 2020 09:49:07

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-14T04:48:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4c6fecdl-dad1-4e3f-84e6-b12eac2c18f6'	System	14 Oct 2020 09:49:07
User entered 'No (N)'	System	14 Oct 2020 09:49:07

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-14T04:49:03', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '4c6fecdl-dad1-4e3f-84e6-b12eac2c18f6' User entered '14 Oct 2020 04:49:03'	System	14 Oct 2020 09:49:07
	System	14 Oct 2020 09:49:07

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 78'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-21T16:08:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'aaafa653-e75f-4136-aa93-706ba5323331'	System	21 Oct 2020 21:08:58
User entered 'Yes (Y)'	System	21 Oct 2020 21:08:58

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-21T16:08:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'aaafa653-e75f-4136-aa93-706ba5323331'	System	21 Oct 2020 21:08:58
User entered 'No (N)'	System	21 Oct 2020 21:08:58



**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-21T16:08:36', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'aaafa653-e75f-4136-aa93-706ba5323331'	System	21 Oct 2020 21:08:58
User entered 'No (N)'	System	21 Oct 2020 21:08:58

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-21T16:08:48', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'aaafa653-e75f-4136-aa93-706ba5323331' User entered 'No (N)'	System	21 Oct 2020 21:08:58
	System	21 Oct 2020 21:08:58

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-10-21T16:08:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'aaafa653-e75f-4136-aa93-706ba5323331' User entered '21 Oct 2020 16:08:56'	System	21 Oct 2020 21:08:58
	System	21 Oct 2020 21:08:58

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 92'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:00:37', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a' User entered 'Yes (Y)'	System	06 Nov 2020 18:02:05
	System	06 Nov 2020 18:02:05

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:00:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a' User entered 'No (N)'	System	06 Nov 2020 18:02:05
	System	06 Nov 2020 18:02:05



**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:00:52', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a' User entered 'No (N)'	System	06 Nov 2020 18:02:05
	System	06 Nov 2020 18:02:05

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:01:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a'	System	06 Nov 2020 18:02:05
User entered 'Yes (Y)'	System	06 Nov 2020 18:02:05

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:01:15', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a'	System	06 Nov 2020 18:02:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 18:02:05

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-06T12:01:20', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69f3064c-4898-4735-a229-434b8ae7337a' User entered '06 Nov 2020 12:01:20'	System	06 Nov 2020 18:02:05
	System	06 Nov 2020 18:02:05

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 99'	System	07 Aug 2020 18:06:52

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-13T12:19:17', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69dbdc89-071f-41ab-a75e-d9f8d358c49e' User entered 'Yes (Y)'	System	13 Nov 2020 18:19:53
	System	13 Nov 2020 18:19:53



**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-13T12:19:26', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69dbdc89-071f-41ab-a75e-d9f8d358c49e' User entered 'No (N)'	System	13 Nov 2020 18:19:53
	System	13 Nov 2020 18:19:53

**US3062151**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-13T12:19:35', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69dbdc89-071f-41ab-a75e-d9f8d358c49e' User entered 'No (N)'	System	13 Nov 2020 18:19:53
	System	13 Nov 2020 18:19:53

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-13T12:19:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69dbdc89-071f-41ab-a75e-d9f8d358c49e'	System	13 Nov 2020 18:19:53
User entered 'No (N)'	System	13 Nov 2020 18:19:53

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-13T12:19:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '69dbdc89-071f-41ab-a75e-d9f8d358c49e' User entered '13 Nov 2020 12:19:49'	System	13 Nov 2020 18:19:53
	System	13 Nov 2020 18:19:53

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered 'Day 106'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:11:16', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f' User entered 'Yes (Y)'	System	18 Nov 2020 23:12:28
	System	18 Nov 2020 23:12:28



**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:11:23', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f'	System	18 Nov 2020 23:12:28
User entered 'No (N)'	System	18 Nov 2020 23:12:28

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:11:31', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f' User entered 'No (N)'	System	18 Nov 2020 23:12:28
	System	18 Nov 2020 23:12:28

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:11:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f' User entered 'Yes (Y)'	System	18 Nov 2020 23:12:28
	System	18 Nov 2020 23:12:28

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:12:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f'	System	18 Nov 2020 23:12:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 23:12:28

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-18T17:12:17', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '42ec984c-00f0-4064-9af4-d5505cc7b12f' User entered '18 Nov 2020 17:12:17'	System	18 Nov 2020 23:12:28
	System	18 Nov 2020 23:12:28

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:34:17
Data entry locked.	System	07 Aug 2020 18:06:52
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 18:06:52

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:54:47



US3062151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:29

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)
User closed query 'Per CDM CLR(requery) : Kindly clarify the response and if any changes in health has occurred after the questionnaire Kindly update appropriately.Thanks ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:40:57
Query 'Per CDM CLR(requery) : Kindly clarify the response and if any changes in health has occurred after the questionnaire Kindly update appropriately.Thanks ' answered with 'Subject reported this on 11/19/2020, site attempted to contact subject. Subject returned call on 11/25/2020 to report the follow up surgery. This is recorded as SAE follow up #1. ' (Site from DM).	Riley King (b) (4) (b) (4)	18 Mar 2021 14:33:39
User opened query 'Per CDM CLR(requery) : Kindly clarify the response and if any changes in health has occurred after the questionnaire Kindly update appropriately.Thanks ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 04:27:49
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 04:27:49
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Progress note written. ' (Site from DM).	Riley King (b) (4) (b) (4)	11 Mar 2021 20:24:50

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

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)
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:25:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:32:34', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered 'Yes (Y)'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:32:41', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered 'No (N)'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:32:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered 'No (N)'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:33:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered 'Yes (Y)'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Please 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:33:13', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-19T17:33:18', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'c4e138bc-a20b-4638-803a-147a18447b97'	System	19 Nov 2020 23:33:32
User entered '19 Nov 2020 17:33:18'	System	19 Nov 2020 23:33:32

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-23T18:38:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '33679fc3-9396-4b5a-a6cb-13117b021ee2' User entered 'No (N)'	System	24 Nov 2020 00:39:07
	System	24 Nov 2020 00:39:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-23T18:38:48', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '33679fc3-9396-4b5a-a6cb-13117b021ee2' User entered 'No (N)'	System	24 Nov 2020 00:39:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-23T18:39:01', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '33679fc3-9396-4b5a-a6cb-13117b021ee2' User entered '23 Nov 2020 18:39:01'	System	24 Nov 2020 00:39:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-29T07:40:03', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6b2bc66d-56fe-428d-b780-04328c77cf8c'	System	29 Nov 2020 13:40:39
User entered 'Yes (Y)'	System	29 Nov 2020 13:40:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-29T07:40:15', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6b2bc66d-56fe-428d-b780-04328c77cf8c'	System	29 Nov 2020 13:40:39
User entered 'No (N)'	System	29 Nov 2020 13:40:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-29T07:40:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6b2bc66d-56fe-428d-b780-04328c77cf8c'	System	29 Nov 2020 13:40:39
User entered 'No (N)'	System	29 Nov 2020 13:40:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-29T07:40:33', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6b2bc66d-56fe-428d-b780-04328c77cf8c'	System	29 Nov 2020 13:40:39
User entered 'No (N)'	System	29 Nov 2020 13:40:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-11-29T07:40:38', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6b2bc66d-56fe-428d-b780-04328c77cf8c' User entered '29 Nov 2020 07:40:38'	System	29 Nov 2020 13:40:39
	System	29 Nov 2020 13:40:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-08T13:45:17', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6df473b9-36f2-4399-a491-53447e8612c4' User entered 'No (N)'	System	08 Dec 2020 19:45:37
	System	08 Dec 2020 19:45:37

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-08T13:45:21', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6df473b9-36f2-4399-a491-53447e8612c4' User entered 'No (N)'	System	08 Dec 2020 19:45:37

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-08T13:45:32', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6df473b9-36f2-4399-a491-53447e8612c4' User entered '08 Dec 2020 13:45:32'	System	08 Dec 2020 19:45:37
	System	08 Dec 2020 19:45:37

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-13T10:54:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0af9610c-9785-43c1-9b9a-8a1ed46ad150'	System	13 Dec 2020 16:54:15
User entered 'No (N)'	System	13 Dec 2020 16:54:15

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-13T10:54:06', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0af9610c-9785-43c1-9b9a-8a1ed46ad150'	System	13 Dec 2020 16:54:15
User entered 'No (N)'	System	13 Dec 2020 16:54:15



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-13T10:54:10', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '0af9610c-9785-43c1-9b9a-8a1ed46ad150' User entered '13 Dec 2020 10:54:10'	System	13 Dec 2020 16:54:15
	System	13 Dec 2020 16:54:15

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-23T11:44:22', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3e85fea5-7af1-49a0-a5e6-ef1aefd8f5bf' User entered 'No (N)'	System	23 Dec 2020 17:44:35

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-23T11:44:27', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3e85fea5-7af1-49a0-a5e6-ef1aefd8f5bf' User entered 'No (N)'	System	23 Dec 2020 17:44:35

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-23T11:44:33', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '3e85fea5-7af1-49a0-a5e6-ef1aefd8f5bf' User entered '23 Dec 2020 11:44:33'	System	23 Dec 2020 17:44:35

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-29T12:45:50', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '278d4402-a26c-456d-87c9-6cbec47d2527'	System	29 Dec 2020 18:46:01
User entered 'No (N)'	System	29 Dec 2020 18:46:01

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-29T12:45:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '278d4402-a26c-456d-87c9-6cbec47d2527'	System	29 Dec 2020 18:46:01
User entered 'No (N)'	System	29 Dec 2020 18:46:01

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2020-12-29T12:45:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '278d4402-a26c-456d-87c9-6cbec47d2527' User entered '29 Dec 2020 12:45:57'	System	29 Dec 2020 18:46:01
	System	29 Dec 2020 18:46:01

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-03T12:30:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '07b94019-083f-474a-91c7-a7b9651cbf41'	System	03 Jan 2021 18:31:00
User entered 'No (N)'	System	03 Jan 2021 18:31:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-03T12:30:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '07b94019-083f-474a-91c7-a7b9651cbf41'	System	03 Jan 2021 18:31:00
User entered 'No (N)'	System	03 Jan 2021 18:31:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-03T12:30:56', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '07b94019-083f-474a-91c7-a7b9651cbf41' User entered '03 Jan 2021 12:30:56'	System	03 Jan 2021 18:31:00
	System	03 Jan 2021 18:31:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-10T10:13:46', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '21cd90ee-028d-4df0-84fa-5a89b1037cc0'	System	10 Jan 2021 16:13:57
User entered 'No (N)'	System	10 Jan 2021 16:13:57

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-10T10:13:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '21cd90ee-028d-4df0-84fa-5a89b1037cc0'	System	10 Jan 2021 16:13:57
User entered 'No (N)'	System	10 Jan 2021 16:13:57



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-10T10:13:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '21cd90ee-028d-4df0-84fa-5a89b1037cc0' User entered '10 Jan 2021 10:13:53'	System	10 Jan 2021 16:13:57
	System	10 Jan 2021 16:13:57

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-18T13:24:43', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '11da47fd-4b3b-4ff8-9e5d-80bbb3753649' User entered 'No (N)'	System	18 Jan 2021 19:25:05
	System	18 Jan 2021 19:25:05

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-18T13:24:57', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '11da47fd-4b3b-4ff8-9e5d-80bbb3753649' User entered 'No (N)'	System	18 Jan 2021 19:25:05

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-18T13:25:03', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '11da47fd-4b3b-4ff8-9e5d-80bbb3753649' User entered '18 Jan 2021 13:25:03'	System	18 Jan 2021 19:25:05
	System	18 Jan 2021 19:25:05

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-24T11:51:07', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a919ae90-d0fa-453f-a9f9-d3bf4c619e51' User entered 'No (N)'	System	24 Jan 2021 17:51:28

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-24T11:51:19', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a919ae90-d0fa-453f-a9f9-d3bf4c619e51'	System	24 Jan 2021 17:51:28
User entered 'No (N)'	System	24 Jan 2021 17:51:28

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-01-24T11:51:24', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a919ae90-d0fa-453f-a9f9-d3bf4c619e51' User entered '24 Jan 2021 11:51:24'	System	24 Jan 2021 17:51:28

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-02T19:05:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1c53433a-62be-4199-874e-8a277574c616'	System	03 Feb 2021 01:06:07
User entered 'No (N)'	System	03 Feb 2021 01:06:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-02T19:05:51', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1c53433a-62be-4199-874e-8a277574c616'	System	03 Feb 2021 01:06:07
User entered 'No (N)'	System	03 Feb 2021 01:06:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-02T19:06:02', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1c53433a-62be-4199-874e-8a277574c616'	System	03 Feb 2021 01:06:07
User entered '02 Feb 2021 19:06:02'	System	03 Feb 2021 01:06:07

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-07T11:47:49', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e3f9f37-fa2a-4935-85e9-ae0fb0dd0223'	System	07 Feb 2021 17:48:11
User entered 'No (N)'	System	07 Feb 2021 17:48:11

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-07T11:47:54', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e3f9f37-fa2a-4935-85e9-ae0fb0dd0223'	System	07 Feb 2021 17:48:11
User entered 'No (N)'	System	07 Feb 2021 17:48:11



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-07T11:48:09', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1e3f9f37-fa2a-4935-85e9-ae0fb0dd0223' User entered '07 Feb 2021 11:48:09'	System	07 Feb 2021 17:48:11
	System	07 Feb 2021 17:48:11

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-14T09:28:38', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9ab76ebd-ebbf-47fc-9861-0e38b4b08359' User entered 'No (N)'	System	14 Feb 2021 15:28:55
	System	14 Feb 2021 15:28:55

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-14T09:28:47', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9ab76ebd-ebbf-47fc-9861-0e38b4b08359' User entered 'No (N)'	System	14 Feb 2021 15:28:55
	System	14 Feb 2021 15:28:55

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-14T09:28:53', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '9ab76ebd-ebbf-47fc-9861-0e38b4b08359' User entered '14 Feb 2021 09:28:53'	System	14 Feb 2021 15:28:55
	System	14 Feb 2021 15:28:55

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-21T08:59:52', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f20508db-2601-4378-acd9-dcfe1e6af6d9' User entered 'No (N)'	System	21 Feb 2021 15:00:12
	System	21 Feb 2021 15:00:12

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-21T08:59:55', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f20508db-2601-4378-acd9-dcfe1e6af6d9' User entered 'No (N)'	System	21 Feb 2021 15:00:12
	System	21 Feb 2021 15:00:12

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-21T09:00:10', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'f20508db-2601-4378-acd9-dcfe1e6af6d9' User entered '21 Feb 2021 09:00:10'	System	21 Feb 2021 15:00:12
	System	21 Feb 2021 15:00:12

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-28T20:26:06-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6bea321b-66e1-461f-9b47-386cd75a5b57'	System	01 Mar 2021 02:34:42
User entered 'No (N)'	System	01 Mar 2021 02:34:42

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-28T20:26:10-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6bea321b-66e1-461f-9b47-386cd75a5b57'	System	01 Mar 2021 02:34:42
User entered 'No (N)'	System	01 Mar 2021 02:34:42

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-28T20:26:15-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '6bea321b-66e1-461f-9b47-386cd75a5b57'	System	01 Mar 2021 02:34:42
User entered '28 Feb 2021 20:26:15'	System	01 Mar 2021 02:34:42

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-07T11:15:30-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '7251b5f2-24fa-4ab4-9478-e02f37ecc068'	System	07 Mar 2021 17:17:15
User entered 'No (N)'	System	07 Mar 2021 17:17:15

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-07T11:15:34-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '7251b5f2-24fa-4ab4-9478-e02f37ecc068'	System	07 Mar 2021 17:17:15
User entered 'No (N)'	System	07 Mar 2021 17:17:15



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-07T11:15:40-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '7251b5f2-24fa-4ab4-9478-e02f37ecc068'	System	07 Mar 2021 17:17:15
User entered '07 Mar 2021 11:15:40'	System	07 Mar 2021 17:17:15

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-14T12:42:29-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '88c7d2d2-c0b5-4a0c-b18b-f9072a2613d1' User entered 'No (N)'	System	14 Mar 2021 17:42:51
	System	14 Mar 2021 17:42:51

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-14T12:42:42-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '88c7d2d2-c0b5-4a0c-b18b-f9072a2613d1'	System	14 Mar 2021 17:42:51
User entered 'No (N)'	System	14 Mar 2021 17:42:51

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-14T12:42:46-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '88c7d2d2-c0b5-4a0c-b18b-f9072a2613d1' User entered '14 Mar 2021 12:42:46'	System	14 Mar 2021 17:42:51
	System	14 Mar 2021 17:42:51

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-22T15:29:08-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '97abab9e-cc1f-4935-8785-1a7f019c0a56'	System	22 Mar 2021 20:29:39
User entered 'No (N)'	System	22 Mar 2021 20:29:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-22T15:29:28-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '97abab9e-cc1f-4935-8785-1a7f019c0a56'	System	22 Mar 2021 20:29:39
User entered 'No (N)'	System	22 Mar 2021 20:29:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-22T15:29:35-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '97abab9e-cc1f-4935-8785-1a7f019c0a56'	System	22 Mar 2021 20:29:39
User entered '22 Mar 2021 15:29:35'	System	22 Mar 2021 20:29:39

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-28T09:58:14-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5f4be995-90f6-4843-bbb3-77b6a29b7b01'	System	28 Mar 2021 14:58:34
User entered 'No (N)'	System	28 Mar 2021 14:58:34

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-28T09:58:26-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5f4be995-90f6-4843-bbb3-77b6a29b7b01'	System	28 Mar 2021 14:58:34
User entered 'No (N)'	System	28 Mar 2021 14:58:34

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-03-28T09:58:30-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '5f4be995-90f6-4843-bbb3-77b6a29b7b01'	System	28 Mar 2021 14:58:34
User entered '28 Mar 2021 09:58:30'	System	28 Mar 2021 14:58:34

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-04T11:59:07-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '301b1fcb-1fa2-4dc9-b6e9-63b08d0c9e29'	System	04 Apr 2021 16:59:35
User entered 'No (N)'	System	04 Apr 2021 16:59:35

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-04T11:59:24-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '301b1fcb-1fa2-4dc9-b6e9-63b08d0c9e29'	System	04 Apr 2021 16:59:35
User entered 'No (N)'	System	04 Apr 2021 16:59:35



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-04T11:59:30-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '301b1fcb-1fa2-4dc9-b6e9-63b08d0c9e29'	System	04 Apr 2021 16:59:35
User entered '04 Apr 2021 11:59:30'	System	04 Apr 2021 16:59:35

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-11T10:29:35-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc9ba960-2ef1-4abc-970e-8446c2126ae4'	System	11 Apr 2021 15:29:45
User entered 'No (N)'	System	11 Apr 2021 15:29:45

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-11T10:29:39-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc9ba960-2ef1-4abc-970e-8446c2126ae4'	System	11 Apr 2021 15:29:45
User entered 'No (N)'	System	11 Apr 2021 15:29:45

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-11T10:29:42-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'fc9ba960-2ef1-4abc-970e-8446c2126ae4'	System	11 Apr 2021 15:29:45
User entered '11 Apr 2021 10:29:42'	System	11 Apr 2021 15:29:45

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-18T15:32:49-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '2f669393-7db6-4f85-b7bb-54cdccf4c054'	System	18 Apr 2021 20:33:00
User entered 'No (N)'	System	18 Apr 2021 20:33:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-18T15:32:52-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '2f669393-7db6-4f85-b7bb-54cdccf4c054'	System	18 Apr 2021 20:33:00
User entered 'No (N)'	System	18 Apr 2021 20:33:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-18T15:32:55-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '2f669393-7db6-4f85-b7bb-54cdccf4c054'	System	18 Apr 2021 20:33:00
User entered '18 Apr 2021 15:32:55'	System	18 Apr 2021 20:33:00

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-25T13:30:57-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1edb9671-d022-4a51-a8dc-6cf98cd07c00'	System	25 Apr 2021 18:31:09
User entered 'No (N)'	System	25 Apr 2021 18:31:09

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-25T13:31:04-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1edb9671-d022-4a51-a8dc-6cf98cd07c00'	System	25 Apr 2021 18:31:09
User entered 'No (N)'	System	25 Apr 2021 18:31:09

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-04-25T13:31:08-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '1edb9671-d022-4a51-a8dc-6cf98cd07c00'	System	25 Apr 2021 18:31:09
User entered '25 Apr 2021 13:31:08'	System	25 Apr 2021 18:31:09

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-05-02T20:24:09-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '165c9ddc-3676-4876-9181-00cc281088e8'	System	03 May 2021 01:24:28
User entered 'No (N)'	System	03 May 2021 01:24:28

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

Have you been exposed to someone with 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 (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-05-02T20:24:20-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '165c9ddc-3676-4876-9181-00cc281088e8'	System	03 May 2021 01:24:28
User entered 'No (N)'	System	03 May 2021 01:24:28



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-05-02T20:24:23-05:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: '165c9ddc-3676-4876-9181-00cc281088e8'	System	03 May 2021 01:24:28
User entered '02 May 2021 20:24:23'	System	03 May 2021 01:24:28

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:54:47



**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:54:47
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:54:47

**US3062151**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:04:29**

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)	24 Apr 2021 23:04:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-28T20:26:22-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a6512132-9b84-4e81-b0ce-5d02fc97bae0'	System	01 Mar 2021 02:34:58
User entered 'No (N)'	System	01 Mar 2021 02:34:58

**US3062151**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:04:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E19036FC-94AA-4692-AF3C-7DAE87438CD9)', Time: '2021-02-28T20:26:28-06:00', User OID: 'PatientReportedOutcome (US3062151)', ODM File OID: 'a6512132-9b84-4e81-b0ce-5d02fc97bae0' User entered '28 Feb 2021 20:26:28'	System	01 Mar 2021 02:34:58
	System	01 Mar 2021 02:34:58

**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:49:09
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Nov 2020 16:27:20
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:49:09
User entered '29 Oct 2020'	Sherry Henning (b) (4)	17 Nov 2020 16:27:20
	(b) (4)	



**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:49:09
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	17 Nov 2020 16:27:20
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:49:09
User entered empty.	Sherry Henning (b) (4)	17 Nov 2020 16:27:20
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:49:16
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Nov 2020 16:27:27
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:15
User entered 'I'	System	17 Nov 2020 16:27:27

**US3062151**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:04:29
User entered 'Yes (Y)'	Riley King (b) (4)	16 Dec 2020 15:20:33
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'please verify PD for oow call (window 30Nov-6Dec)' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:47:12
Query 'please verify PD for oow call (window 30Nov-6Dec)' answered with 'will verify' (Site from CRA).	Colton King (b) (4)	03 Feb 2021 21:49:44
	(b) (4)	
User opened query 'please verify PD for oow call (window 30Nov-6Dec)' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 16:07:39
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:04:29
	(b) (4)	
User entered '8 Dec 2020'	Riley King (b) (4)	16 Dec 2020 15:20:33
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:04:29
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	16 Dec 2020 15:20:33
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:04:29
User entered empty.	Riley King (b) (4)	16 Dec 2020 15:20:33
	(b) (4)	



US3062151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:04:39
User entered 'Yes (Y)'	Riley King (b) (4)	16 Dec 2020 15:20:37
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'I'	System	16 Dec 2020 15:20:37

**US3062151**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:15:43
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 22:59:14
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:15:43
User entered '31 Dec 2020'	Riley King (b) (4)	05 Jan 2021 22:59:14
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:15:43
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	05 Jan 2021 22:59:14
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:15:43
User entered empty.	Riley King (b) (4)	05 Jan 2021 22:59:14
	(b) (4)	

US3062151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:15:52
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 22:59:06
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'I'	System	05 Jan 2021 22:59:06



**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:58:39
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 21:30:16
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:58:39
User entered '29 Jan 2021'	Colton King (b) (4)	04 Feb 2021 21:30:16
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:58:39
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	04 Feb 2021 21:30:16
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:58:39
User entered empty.	Colton King (b) (4)	04 Feb 2021 21:30:16
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 21:30:21
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'I'	System	04 Feb 2021 21:30:21

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	24 Mar 2021 14:42:05

US3062151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'PD routing' (Site from System).	Colton King (b) (4)	24 Mar 2021 14:47:34
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 14:42:05
User entered '22 Mar 2021'	Colton King (b) (4)	24 Mar 2021 14:42:05



US3062151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4) (b) (4)	24 Mar 2021 14:42:05

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'VISIT4'	System	24 Mar 2021 14:42:05

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '22 Mar 2021'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '13:31'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered '22 Mar 2021 13:31'	System	01 Apr 2021 18:58:25

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '98.6' F	marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'Oral (Oral)'	marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	



**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '80'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'bpm'	System	01 Apr 2021 18:58:25

US3062151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '16'	marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'breaths/min'	System	01 Apr 2021 18:58:25

US3062151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '97'	marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'mmHg'	System	01 Apr 2021 18:58:25

US3062151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '65'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 18:58:25
	(b) (4)	



**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'mmHg'	System	01 Apr 2021 18:58:25

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:04:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	24 Mar 2021 14:48:14
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:04:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:23:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered empty.	Colton King (b) (4)	24 Mar 2021 14:48:14
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:24:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	24 Mar 2021 14:48:59

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:24:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '22 Mar 2021'	(b) (4) Colton King (b) (4) (b) (4)	24 Mar 2021 14:48:59

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:24:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '13:47'	(b) (4) Colton King (b) (4)	24 Mar 2021 14:48:59



**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered '22 Mar 2021 13:47'	System	24 Mar 2021 14:48:59

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:21:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	24 Mar 2021 14:49:24
	(b) (4)	

**US3062151**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:47:59
User entered 'I'	System	24 Mar 2021 14:49:24

**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:31
User entered 'Yes (Y)'	Colton King (b) (4)	02 Apr 2021 21:03:12
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:31
User entered '2 Apr 2021'	Colton King (b) (4)	02 Apr 2021 21:03:12
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:31
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	02 Apr 2021 21:03:12
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:31
User entered empty.	Colton King (b) (4)	02 Apr 2021 21:03:12
	(b) (4)	

**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:12:29
User entered 'Yes (Y)'	Colton King (b) (4)	02 Apr 2021 21:02:50
	(b) (4)	



**US3062151**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:32
User entered 'I'	System	02 Apr 2021 21:02:50

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:59:21
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:24

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:59:21
User entered '29 Jan 2021'	Janna Martinez (b) (4)	30 Jan 2021 19:18:24
	(b) (4)	

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:29

[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 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:59:21
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:24
	(b) (4)	

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User entered 'UNBLND_DECIDE'	System	30 Jan 2021 19:18:24

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:04:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered '29 Jan 2021'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[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 08:04:32
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered '0'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 15:14:32
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:21:30

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53



**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:11:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	marissa Mueller (b) (4)	31 Mar 2021 15:14:32
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:21:30

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered '29 Jan 2021'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:04:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered 'mRNA-1273 (mRNA-1273)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:04:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered 'mRNA-1273 (mRNA-1273)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53
	(b) (4)	

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered 'mRNA-1273 (mRNA-1273)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:04:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:02
User entered 'No (N)'	Janna Martinez (b) (4)	30 Jan 2021 19:18:53
	(b) (4)	

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User entered empty.	System	30 Jan 2021 19:18:53

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:29**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User entered empty.	System	30 Jan 2021 19:18:53



**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:42
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Jan 2021 19:19:19

US3062151

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:42
User entered '29 Jan 2021'	Janna Martinez (b) (4)	30 Jan 2021 19:19:19

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:42
User entered '11:03' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Jan 2021 19:19:28
User entered '10:03'	Janna Martinez (b) (4)	30 Jan 2021 19:19:19

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User entered '29 Jan 2021 11:03'	System	30 Jan 2021 19:19:28
User entered '29 Jan 2021 10:03'	System	30 Jan 2021 19:19:19

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:49
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Jan 2021 19:19:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:04:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:49
User entered '29 Jan 2021'	Janna Martinez (b) (4)	30 Jan 2021 19:19:39
	(b) (4)	

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:00:49
User entered '11:00'	Janna Martinez (b) (4)	30 Jan 2021 19:19:39

**US3062151**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:29**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:04:32
User entered '29 Jan 2021 11:00'	System	30 Jan 2021 19:19:39



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:04:29**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:42:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	20 Oct 2020 21:14:52
User entered 'No (N)'	marissa Mueller (b) (4)	02 Sep 2020 14:15:40
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:00
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 18:26:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'Per DM CLR: RQ: Response noted, however, if this is not a worsening this should be removed from this page. Only worsening of a baseline medical condition should be recorded. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:23:04
Query 'Per DM CLR: RQ: Response noted, however, if this is not a worsening this should be removed from this page. Only worsening of a baseline medical condition should be recorded. Otherwise, clarify.' answered with 'Per (b) (6) on 8/7/2020 the underlying medical condition that requires hip replacement would be considered the AE. If the subject requires hospitalization during the study to have treatment this AE is considered an SAE.' (Site from DM).	Riley King (b) (4) (b) (4)	29 Jan 2021 21:35:45
User opened query 'Per DM CLR: RQ: Response noted, however, if this is not a worsening this should be removed from this page. Only worsening of a baseline medical condition should be recorded. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:02:19
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Osteoarthritis of Hips. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:20:27
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Osteoarthritis of Hips. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'This is not worsening. The surgery for this was pre-planned prior to subject's entry into the study. ' (Site from DM).	Jeri King (b) (4)	21 Nov 2020 14:44:43
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Osteoarthritis of Hips. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:27:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 23:01:52
Query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' answered with 'per medical monitor via epip 393216' (Site from Safety).	marissa Mueller (b) (4)	30 Oct 2020 20:42:18
User opened query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:19:32
User closed query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:01:50
Query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' answered with 'per medical monitor, event meets SAE criteria as it required hospitalization ' (Site from Safety).	marissa Mueller (b) (4)	29 Oct 2020 21:01:18
User opened query 'PV Query: Please provide the investigator's rationale for assessing the left hip osteoarthritis as a valid SAE as it is part of the subject's medical history and the replacement procedure had been planned prior to screening.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:12:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:22:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:22:27
Data point term sent to Coder	System	20 Oct 2020 21:21:37
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:03:21
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Yes (Y)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:46:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:46:56
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:21:00



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:46:58
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '14 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:02
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '15 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:12
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:08
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Grade 4 (Grade 4)'	Jeri King (b) (4)	20 Oct 2020 21:21:00



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Yes (Y)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:15
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:19
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'I'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:21
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '14 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '15 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:21:00



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:29
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:36
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:38
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:42
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:45
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:45:24
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:45:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
DataPoint Un-verified.	Riley King (b) (4)	26 Feb 2021 15:51:06
User entered '1' reason for change: Per Query Resolution	Riley King (b) (4)	26 Feb 2021 15:51:06
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:45:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered '0'	Jeri King (b) (4)	20 Oct 2020 21:21:00



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'I'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:54
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:55
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:21:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:47:57
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:24:22
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:31:22
User entered 'DURING SCREENING, SUBJECT REPORTED THAT A LEFT HIP REPLACEMENT WAS PLANNED. SUBJECT HAD THE PROCEDURE ON 10/14/2020. SUBJECT ADMITTED TO HOSPITAL ON 10/14/2020 AND PROCEDURE PERFORMED. SUBJECT WAS DISCHARGED FROM THE HOSPITAL IN STABLE CONDITION ON 10/15/2020. RELEASE OF RECORDS SENT TO HOSPITAL 10/20/2020 11/25/2020 Hospital Records received. Medications updated per conmed form. No change in other information previously reported.' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:31:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:50:56
User entered 'During screening, subject reported that a left hip replacement was planned. Subject had the procedure on 10/14/2020. Subject admitted to hospital on 10/14/2020 and procedure performed. Subject was discharged from the hospital in stable condition on 10/15/2020. Release of records sent to hospital 10/20/2020'	Jeri King (b) (4)	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 21:21:00

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:26:07
User entered 'USA-US090-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	30 Oct 2020 14:26:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:38:37
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative wound infection, LLT: Post procedural site wound infection - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 11:15:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 11:15:26
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 20:24:21
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:23:33
	(b) (4)	
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 20:23:33
	(b) (4)	
User entered 'POST OP WOUND INFECTION, L hip' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:23:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative wound infection, LLT: Postoperative wound infection - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:02:02
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:02:02
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 21:07:11
User entered 'post op wound infection'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:06:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Jan 2021 20:24:06
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:24:06
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:24:06
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Jan 2021 20:23:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	



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Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:53:23
User closed query 'please verify as 12Dec2020 per AE log' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:53:19
Query 'please verify as 12Dec2020 per AE log' answered with 'updated' (Site from CRA).	Colton King (b) (4)	04 Feb 2021 21:34:44
User entered '12 Dec 2020' reason for change: New Information	(b) (4)	04 Feb 2021 21:34:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:38
DataPoint Verified.		03 Feb 2021 19:07:02
User opened query 'please verify as 12Dec2020 per AE log' (Site from CRA).		03 Feb 2021 17:10:49
DataPoint Un-verified.		03 Feb 2021 17:09:53
DataPoint Verified.		03 Feb 2021 17:02:35
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:23:33
User entered '25 Oct 2020' reason for change: New Information	(b) (4)	29 Jan 2021 20:23:33
DataPoint Verified.	(b) (4)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:09:51
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:06:15

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Grade 4 (Grade 4)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

US3062151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Oct 2020 21:06:33
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Oct 2020 21:06:15
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

US3062151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Oct 2020 21:06:33
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).		29 Oct 2020 21:06:33
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	29 Oct 2020 21:06:33
	(b) (4)	
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	29 Oct 2020 21:06:15
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '28 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'I'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'I'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:41:03
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)	01 Feb 2021 17:26:05
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 'Recovered. ' (Site from Safety).	Riley King (b) (4)	29 Jan 2021 20:23:54
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:23:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Riley King (b) (4)	29 Jan 2021 20:23:33
Data Entry Error	(b) (4)	
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)	05 Nov 2020 21:28:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:06:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:26:32
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:26:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' answered with 'Emailed to Safety_Moderna@iqvia.com. ' (Site from Safety).	Riley King (b) (4) (b) (4)	29 Jan 2021 21:04:01
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Emailed to Safety_Moderna@iqvia.com. ' (Site from Safety).	Riley King (b) (4) (b) (4)	29 Jan 2021 21:03:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:37:05
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)	09 Nov 2020 21:22:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4) (b) (4)	06 Nov 2020 23:14:45



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 21:29:13
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)	05 Nov 2020 21:28:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Subject contacted 10/29/2020 for Day 85 call. During call, subject reports that she was released from the hospital on 10/28/2020. Subject reported that she was admitted to the hospital on 10/20/2020 for a postoperative wound infection. During the hospitalization she had a revision to her left hip replacement. The left hip replacement was performed on 10/14/2020. Release of records mailed to subject.'	marissa Mueller (b) (4)	29 Oct 2020 21:06:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:06:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:06:15

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 21:06:15

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Feb 2021 00:14:47
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 00:14:47
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
Data point term sent to Coder	System	29 Jan 2021 21:26:14
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 21:25:20
User entered 'POST OPERATIVE PAIN, generalized' reason for change: Data Entry Error	(b) (4)	29 Jan 2021 21:25:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\23.0.	Riley King (b) (4)	29 Jan 2021 21:25:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 23:29:11
Data point term sent to Coder	(b) (4)	25 Nov 2020 23:28:02
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:27:18
Coding entries removed.	Jeri King (b) (4)	25 Nov 2020 23:27:18
User entered 'POST Operative PAIN' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:27:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:13:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:13:23
Data point term sent to Coder	System	30 Oct 2020 20:40:48
User entered 'post op pain'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:25:44
	(b) (4)	
User entered '24 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 22:25:44
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:52:50
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:27:36
User entered '14 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:27:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '20 Oct 2020'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User entered empty.	System	30 Oct 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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.	(b) (4), (b) (6)	03 Feb 2021 09:04:34
' (Site from DM).		
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.	Riley King (b) (4)	29 Jan 2021 22:27:49
' answered with 'reconciled ' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:25:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 22:25:44
	(b) (4)	
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.	(b) (4), (b) (6)	09 Jan 2021 05:03:05
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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	29 Jan 2021 22:27:42
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	29 Jan 2021 22:27:42
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	29 Jan 2021 22:25:44
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:25:44
	(b) (4)	
User entered '12 Dec 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 22:25:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User entered empty.	System	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

US3062151

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 20:40:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 20:40:20
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	30 Oct 2020 20:40:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 20:40:16
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'I'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:27:42
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 22:27:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User entered '0'	System	30 Oct 2020 20:40:20

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06
User entered '1'	System	30 Oct 2020 20:40:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:06

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Procedural nausea, LLT: Post procedural nausea - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 01:00:08
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	(b) (4)	31 Oct 2020 01:00:08
Data point term sent to Coder	System	30 Oct 2020 20:41:48
User entered 'post op nausea recurrent'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:05
User closed query 'please verify as 14Oct2020 per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:47:01
Query 'please verify as 14Oct2020 per CM log' answered with 'updated' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:20:29
User entered '14 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 20:20:23
User opened query 'please verify as 14Oct2020 per CM log' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 17:51:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 17:51:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '20 Oct 2020'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User entered empty.	System	30 Oct 2020 20:40:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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)	03 Feb 2021 09:04:55
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 'Reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	29 Jan 2021 22:41:58
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	29 Jan 2021 22:41:29
User entered 'No (N)' reason for change: New Information	Riley King (b) (4) (b) (4)	29 Jan 2021 22:41:29
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)	09 Jan 2021 05:03:16
DataPoint Verified.	Stephan Penn (b) (4) (b) (4)	04 Nov 2020 18:51:03
User entered 'Yes (Y)'	marissa Mueller (b) (4) (b) (4)	30 Oct 2020 20:40:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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	29 Jan 2021 22:41:51
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	29 Jan 2021 22:41:51
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	29 Jan 2021 22:41:29
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:41:29
	(b) (4)	
User entered '30 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 22:41:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User entered empty.	System	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'No (N)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

US3062151

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

US3062151

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58



US3062151

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

US3062151

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'l'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered '0'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:04:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:41:51
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Riley King (b) (4)	29 Jan 2021 22:41:51
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:51:03
User entered empty.	marissa Mueller (b) (4)	30 Oct 2020 20:40:58
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User entered '0'	System	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09
User entered '1'	System	30 Oct 2020 20:40:58

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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)	30 Jan 2021 20:49:28
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	(b) (4)	30 Jan 2021 20:49:28
Data point term sent to Coder	System	29 Jan 2021 21:30:22
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:30:12
Coding entries removed.	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 21:30:12
User entered 'CONSTIPATION, intermittent' reason for change: Per Query Resolution	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 21:30:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 17:53:12
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)	25 Nov 2020 23:30:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 23:30:57
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 23:30:03
User entered 'Constipation'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:14
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:29:13



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:16
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:17
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:19
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:22
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User entered empty.	System	25 Nov 2020 23:29:13

US3062151

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:26:10
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Un-verified.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:05:22
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Occurs intermittently ' (Site from DM).	Riley King (b) (4) (b) (4)	29 Jan 2021 21:30:10
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:03:34
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:24
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

US3062151

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:26:10
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Un-verified.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:26
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:28
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User entered empty.	System	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:32
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:34
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:36
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:38
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:40
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:42
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:46
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:44
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:48
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:52
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:54
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:53:59
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:01
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:04:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 17:54:03
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 23:29:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:29:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:13
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:06
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:09
User entered 'I'	Jeri King (b) (4)	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:12
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:26:10
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Un-verified.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	24 Mar 2021 14:15:13
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:17
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:29:13

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User entered '0'	System	25 Nov 2020 23:29:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25
User entered '1'	System	25 Nov 2020 23:29:13



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	30 Jan 2021 20:29:28
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	30 Jan 2021 20:29:28
DataPoint Un-verified.	(b) (4)	
	System	29 Jan 2021 20:17:16
	Riley King (b) (4)	29 Jan 2021 20:17:03
	(b) (4)	
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 20:17:03
	(b) (4)	
User entered 'ANEMIA, intermittent' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:17:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 17:54:25
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 23:31:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	25 Nov 2020 23:31:58
User entered 'Anemia'	(b) (4)	
	System	25 Nov 2020 23:31:04
	Jeri King (b) (4)	25 Nov 2020 23:30:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:27
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:29
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:31
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:34
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:36
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 23:30:09



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
DataPoint Un-verified.	Colton King (b) (4)	04 Feb 2021 21:37:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	04 Feb 2021 21:37:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
	(b) (4), (b) (6)	
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).		03 Feb 2021 09:05:32
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Added intermittent to AE term. AE recovered at this time. ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 20:21:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:20:13
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:17:21
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:17:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 20:17:03
	(b) (4)	
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:03:42
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:38

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EAB) (1725)

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**Folder: Adverse Events**

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[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'please reconcile date with AE log' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 19:21:27
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
User closed query 'please verify venofer given 27Oct per hos record' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:59:04
Query 'please reconcile date with AE log' answered with 'AE ongoing.' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:26:51
Query 'please verify venofer given 27Oct per hos record' answered with 'She did get the venofer on 10/27/2020.' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:26:41
User closed query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 22:26:15
Query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Feb 2021 22:26:15
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 21:37:02
User entered empty; reason for change New Information	Colton King (b) (4)	04 Feb 2021 21:37:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:57
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
User opened query 'please verify venofer given 27Oct per hos record' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:26:14
User opened query 'please reconcile date with AE log' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:12:42
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:12:15
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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	29 Jan 2021 20:20:29

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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	29 Jan 2021 20:20:29
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	29 Jan 2021 20:20:13
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 20:20:13
	(b) (4)	
User entered '25 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 20:20:13
	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Jan 2021 20:17:21
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Jan 2021 20:17:03
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:40
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:12:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:42
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:45
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:30:09



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:48
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:50
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:52
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:54
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:56
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:54:58
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:00
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:03
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:07
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:09
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:11
User entered 'Not Related (NOT RELATED)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:13
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	25 Nov 2020 23:30:09

US3062151

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
DataPoint Un-verified.	Riley King (b) (4)	04 Feb 2021 22:17:01
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	04 Feb 2021 22:17:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
DataPoint Un-verified.		03 Feb 2021 17:53:11
DataPoint Verified.		03 Feb 2021 17:02:35
DataPoint Un-verified.		02 Dec 2020 18:40:24
DataPoint Verified.		02 Dec 2020 17:55:16
User entered '1'	Jeri King (b) (4)	25 Nov 2020 23:30:09

US3062151

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
User closed query 'please verify venofer given for anemia' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:59:18
User closed query 'please verify subject received PRBC transfusion on 21Oct2020 per CM log' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:59:13
Query 'please verify venofer given for anemia' answered with 'She did receive Venofer, this has been changed to reflect that. ' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:19:08
Query 'please verify subject received PRBC transfusion on 21Oct2020 per CM log' answered with 'She did receive the transfusion, but it was for the GI bleed, not the anemia. ' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:18:41
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	04 Feb 2021 22:17:01
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:08:02
DataPoint Verified.		03 Feb 2021 19:07:02
User opened query 'please verify venofer given for anemia' (Site from CRA).		03 Feb 2021 18:26:46
User opened query 'please verify subject received PRBC transfusion on 21Oct2020 per CM log' (Site from CRA).		03 Feb 2021 17:53:53
DataPoint Un-verified.		03 Feb 2021 17:53:14
DataPoint Verified.		03 Feb 2021 17:02:35
DataPoint Un-verified.		02 Dec 2020 18:40:29
DataPoint Verified.		02 Dec 2020 17:55:19
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:24
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:30:09



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
DataPoint Un-verified.	Riley King (b) (4)	04 Feb 2021 22:26:15
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Riley King (b) (4)	04 Feb 2021 22:26:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 20:20:29
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jeri King (b) (4)	25 Nov 2020 23:30:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:55:28
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 23:30:09

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 23:30:09

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:38:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:38:22
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 19:38:01
User entered 'Hiatal hernia'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:37:04

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:37:04



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:37:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 19:37:04

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 19:37:04

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:30:39
User entered 'USA-US090-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	01 Feb 2021 17:30:22



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:40:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:40:40
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 19:40:02
User entered 'Non cardiac chest pain'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:39:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:39:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 4 (Grade 4)' reason for change:	Riley King (b) (4)	29 Jan 2021 21:11:44
Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:53:48
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'No treatment given ' (Site from DM).	Riley King (b) (4)	26 Feb 2021 16:19:35
	(b) (4)	
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:08:47
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'Per DM CLR: Narrative = CONFUSION. 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)	09 Mar 2021 20:47:31
User closed query 'Per DM CLR: Narrative = POSSIBLE RIGHT BUNDLE BRANCH BLOCK ON 24OCT2020. 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)	09 Mar 2021 20:46:25
User closed query 'Per DM CLR: Narrative = REPEAT TROPONIN AND ECG. However, these were 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)	09 Mar 2021 20:45:58
Query 'Per DM CLR: Narrative = CONFUSION. 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 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	02 Mar 2021 20:42:22
	(b) (4)	
Query 'Per DM CLR: Narrative = POSSIBLE RIGHT BUNDLE BRANCH BLOCK ON 24OCT2020. 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 'No, it shouldn't. To confirm if bundle branch block is present subject would need further testing. ' (Site from DM).	Riley King (b) (4)	02 Mar 2021 14:20:41
	(b) (4)	
Query 'Per DM CLR: Narrative = REPEAT TROPONIN AND ECG. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	02 Mar 2021 14:20:00
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = CONFUSION. 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)	15 Feb 2021 02:09:08
User opened query 'Per DM CLR: Narrative = POSSIBLE RIGHT BUNDLE BRANCH BLOCK ON 24OCT2020. 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)	15 Feb 2021 02:09:01
User opened query 'Per DM CLR: Narrative = REPEAT TROPONIN AND ECG. However, these were 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)	15 Feb 2021 02:08:54
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Jan 2021 19:52:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Jan 2021 19:52:56
User entered 'Prior to discharge on 23OCT2020 subject reported chest pain. Decision was made to cancel discharge and repeat troponin and ECG. Troponin results were normal and ECG sinus tachycardia with possible right bundle branch block on 24OCT2020. Medical records state they believe the chest pain was possibly related to her duodenal ulcer. On 24OCT2020, subject developed 102.0 fever and confusion. See additional SAE.' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	29 Jan 2021 19:52:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Jan 2021 19:39:03
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 19:39:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 19:39:03

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 19:39:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 19:39:03

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:40:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 19:40:03
User entered 'Suicidal ideation'	Riley King (b) (4)	29 Jan 2021 19:39:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:51

US3062151

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:11:24
DataPoint Un-verified.	Riley King (b) (4)	04 Feb 2021 22:27:41
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 22:27:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User entered empty.	System	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:51

US3062151

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:11:21
User closed query 'please reconcile end date per AE log' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:11:17
Query 'please reconcile end date per AE log' answered with 'Reconciled' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:27:56
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
	System	04 Feb 2021 22:27:41
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	04 Feb 2021 22:27:23
User entered '21 Oct 2020' reason for change: Per Query Resolution	Riley King (b) (4)	04 Feb 2021 22:27:23
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:08:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:07:02
User opened query 'please reconcile end date per AE log' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:08:37
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:07:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
	(b) (4), (b) (6)	
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:39:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User entered empty.	System	29 Jan 2021 19:39:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:39:51

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
User closed query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:46:09
Query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance ' answered with 'this event does not meet serious criteria due to its medical significance ' (Site from DM).	Janna Martinez (b) (4)	01 Mar 2021 18:29:54
User opened query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:45:32
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:39:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:39:51

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User entered '0'	System	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29
User entered '1'	System	29 Jan 2021 19:39:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:29



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Malnutrition, LLT: Unspecified nutritional deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:41:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:41:22
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 19:41:04
User entered 'Nutritional deficiency'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:40:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:40:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

US3062151

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:40:36
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 19:40:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 19:40:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49

US3062151

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:42:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:42:22
Data point term sent to Coder	System	29 Jan 2021 19:42:05
User entered 'Gastritis'	Riley King (b) (4)	29 Jan 2021 19:41:51
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:41:51

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:41:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:41:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User entered empty.	System	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:41:51

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '30 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User entered empty.	System	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:41:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:41:51



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User entered '0'	System	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49
User entered '1'	System	29 Jan 2021 19:41:51

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:49

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52

US3062151

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Oesophagitis, LLT: Esophagitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:43:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:43:24
Data point term sent to Coder	System	29 Jan 2021 19:43:06
User entered 'Esophagitis'	Riley King (b) (4)	29 Jan 2021 19:42:38
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '22 Oct 2020'	Riley King (b) (4)	03 Feb 2021 17:02:35
	(b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User entered empty.	System	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '5 Nov 2020'	Riley King (b) (4)	29 Jan 2021 19:42:38



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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User entered empty.	System	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Riley King (b) (4)	(b) (4)

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:42:38



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User entered '0'	System	29 Jan 2021 19:42:38



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52
User entered '1'	System	29 Jan 2021 19:42:38

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:52

US3062151

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Colonic diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:44:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:44:23
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 19:44:07
User entered 'Colonic diverticulosis'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:43:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:43:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

US3062151

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:43:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 19:43:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 19:43:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11

US3062151

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Leg edema - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:15:28
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	30 Jan 2021 21:15:28
Data point term sent to Coder	System	29 Jan 2021 19:45:14
User entered 'Edema, left lower extremity'	Riley King (b) (4)	29 Jan 2021 19:44:23
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:44:23



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User entered empty.	System	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User entered empty.	System	29 Jan 2021 19:44:23



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

US3062151

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:04:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

US3062151

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 19:44:23



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User entered '0'	System	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11
User entered '1'	System	29 Jan 2021 19:44:23

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:04:11



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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 19:47:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Jan 2021 19:47:22
Data point term sent to Coder	System	29 Jan 2021 19:46:14
User entered 'Sinus tachycardia'	Riley King (b) (4)	29 Jan 2021 19:45:31
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:45:31

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:45:31

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User entered empty.	System	29 Jan 2021 19:45:31



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User entered empty.	System	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User entered '0'	System	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43
User entered '1'	System	29 Jan 2021 19:45:31

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:15:43

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33

US3062151

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
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)	29 Jan 2021 19:48:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Jan 2021 19:48:32
Data point term sent to Coder	System	29 Jan 2021 19:47:15
User entered 'Hypotension'	Riley King (b) (4)	29 Jan 2021 19:46:34
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:46:34



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User entered empty.	System	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User entered empty.	System	29 Jan 2021 19:46:34



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

US3062151

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User entered '0'	System	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33
User entered '1'	System	29 Jan 2021 19:46:34

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:33



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03

US3062151

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jan 2021 20:48:47
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	(b) (4)	31 Jan 2021 20:48:47
Data point term sent to Coder	System	29 Jan 2021 19:48:16
User entered 'Hematoma left hip'	Riley King (b) (4)	29 Jan 2021 19:47:16
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User entered empty.	System	29 Jan 2021 19:47:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User entered empty.	System	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User entered '0'	System	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03
User entered '1'	System	29 Jan 2021 19:47:16

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:03

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05

US3062151

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 20:05:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 20:05:22
Data point term sent to Coder	System	29 Jan 2021 19:49:17
User entered 'Abdominal pain'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:48:28



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '19 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User entered empty.	System	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User entered empty.	System	29 Jan 2021 19:48:28



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 19:48:28



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

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**Folder: Adverse Events**

**Form: Adverse Events (18)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User entered '0'	System	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05
User entered '1'	System	29 Jan 2021 19:48:28

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:03:05



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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:32:04
User entered	(b) (4), (b) (6)	01 Feb 2021 17:31:57
'USA-US090-2020-mRNA-1273-P301000005'		

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: Gastrointestinal bleed - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:18:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:18:23
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 21:18:07
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:04:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 21:18:04



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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Nov 2020'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 21:18:04

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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**Folder: Adverse Events**

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:18:04
	(b) (4)	



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Form: Adverse Events (19)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
User closed query 'Per DM CLR: Narrative = EVIDENCE OF ACUTE DIVERTICULITIS. 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)	15 Mar 2021 08:50:55
Query 'Per DM CLR: Narrative = EVIDENCE OF ACUTE DIVERTICULITIS. 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 'was not diagnosed. ' (Site from DM).	marissa Mueller (b) (4)	11 Mar 2021 17:52:56
User opened query 'Per DM CLR: Narrative = EVIDENCE OF ACUTE DIVERTICULITIS. 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 Mar 2021 12:31:56
User closed query 'Per DM CLR: Narrative = COLONIC DIVERTICULITIS. However, AE #13 is COLONIC DIVERTICULOSIS. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:43:45
User closed query 'Per DM CLR: Narrative = CT PERFORMED ON 21OCT2020 . 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)	09 Mar 2021 20:43:43
User closed query 'Per DM CLR: Narrative = EGD ON22OCT2020. 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)	09 Mar 2021 20:43:39
User closed query 'Per DM CLR: Narrative = WEAKNESS, SYNCOPE EPISODE. 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)	09 Mar 2021 20:43:29

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:20:12
Query 'Per DM CLR: Narrative = WEAKNESS, SYNCOPE EPISODE. 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 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	02 Mar 2021 20:44:46
Query 'Per DM CLR: Narrative = EGD ON22OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	02 Mar 2021 20:44:43
Query 'Per DM CLR: Narrative = CT PERFORMED ON 21OCT2020 . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'DATA CORRECTED' (Site from DM).	Janna Martinez (b) (4)	02 Mar 2021 20:44:38
Query 'Per DM CLR: Narrative = COLONIC DIVERTICULITIS. However, AE #13 is COLONIC DIVERTICULOSIS. Please review and reconcile data as appropriate.' answered with 'reconciled' (Site from DM).	Riley King (b) (4)	02 Mar 2021 14:35:03
DataPoint Un-verified.	Riley King (b) (4)	02 Mar 2021 14:34:55
User entered 'SHE PRESENTED TO ER WITH WEAKNESS, BLOOD IN STOOL, AND SYNCOPE EPISODE. EGD ON22OCT2020 REVEALED A HIATAL HERNIA, DUODENITIS, AND MILD GASTRITIS. CT PERFORMED ON 21OCT2020 SHOWED COLONIC Diverticulosis WITHOUT EVIDENCE OF ACUTE DIVERTICULITIS AND HEMATOMA OVERLAYING LEFT HIP. SUBJECT TO BE DISCHARGED ON 23OCT2020 IN STABLE CONDITION WHEN SHE REPORTED CHEST PAIN. DURING HOSPITALIZATION, PATIENT RECEIVED BLOOD TRANSFUSIONS DUE TO LOSS OF BLOOD. SEE ADDITIONAL SAES REGARDING CHEST PAIN AND POP UP WOUND INFECTION, LEFT HIP.' reason for change: Data Entry Error	Riley King (b) (4)	02 Mar 2021 14:34:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:04:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = COLONIC DIVERTICULITIS. However, AE #13 is COLONIC DIVERTICULOSIS. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:08:18
User opened query 'Per DM CLR: Narrative = CT PERFORMED ON 21OCT2020 . 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)	15 Feb 2021 02:08:10
User opened query 'Per DM CLR: Narrative = EGD ON22OCT2020. 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)	15 Feb 2021 02:08:04
User opened query 'Per DM CLR: Narrative = WEAKNESS, SYNCOPE EPISODE. 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)	15 Feb 2021 02:07:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'She presented to ER with weakness, blood in stool, and syncope episode. EGD on22OCT2020 revealed a hiatal hernia, duodenitis, and mild gastritis. CT performed on 21OCT2020 showed colonic diverticulitis without evidence of acute diverticulitis and hematoma overlaying left hip. Subject to be discharged on 23OCT2020 in stable condition when she reported chest pain. During hospitalization, patient received blood transfusions due to loss of blood. See additional SAEs regarding chest pain and pop up wound infection, Left hip.'	Riley King (b) (4) (b) (4)	29 Jan 2021 21:18:04

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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 21:18:04

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 21:18:04

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**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 21:18:04

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 18:13:30
User closed query 'please specify location' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:13:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Excoriation - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 14:34:37
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 14:34:37
Data point term sent to Coder	System	04 Feb 2021 22:29:30
Query 'please specify location' answered with 'Site added ' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:29:26
Coding entries removed.	(b) (4)	
	Riley King (b) (4)	04 Feb 2021 22:29:16
User entered 'EXCORIATION, left hip' reason for change: Per Query Resolution	Riley King (b) (4)	04 Feb 2021 22:29:16
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 19:08:55
User opened query 'please specify location' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:06:49
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Excoriation - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 21:21:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 21:21:24
Data point term sent to Coder	System	29 Jan 2021 21:21:09
User entered 'Excoriation'	Riley King (b) (4)	29 Jan 2021 21:20:13
	(b) (4)	



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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered empty.	System	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:20:13



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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered empty.	System	29 Jan 2021 21:20:13

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13



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**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13
	(b) (4)	

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**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:20:13

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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:20:13



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**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'I'	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered '0'	System	29 Jan 2021 21:20:13



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered '1'	System	29 Jan 2021 21:20:13

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47

US3062151

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:21:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Jan 2021 21:21:24
Data point term sent to Coder	System	29 Jan 2021 21:21:09
User entered 'Duodenal Ulcer'	Riley King (b) (4)	29 Jan 2021 21:20:59
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:20:59



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User entered empty.	System	29 Jan 2021 21:20:59

US3062151

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:30:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 21:30:30
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 21:30:30
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:20:59
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '3 Dec 2020'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User entered empty.	System	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:20:59



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:20:59



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User entered '0'	System	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47
User entered '1'	System	29 Jan 2021 21:20:59

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:47

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56

US3062151

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Gastrointestinal inflammatory disorders NEC, PT: Duodenitis, LLT: Duodenitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:22:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	29 Jan 2021 21:22:23
Data point term sent to Coder	System	29 Jan 2021 21:22:10
User entered 'Duodenitis'	Riley King (b) (4)	29 Jan 2021 21:21:36
	(b) (4)	



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User entered empty.	System	29 Jan 2021 21:21:36

US3062151

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:21:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 21:21:55
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 21:21:55
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 21:21:36
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '5 Nov 2020'	Riley King (b) (4)	29 Jan 2021 21:21:36



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User entered empty.	System	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

US3062151

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 21:21:36



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'l'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered '0'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:02:35
User entered empty.	Riley King (b) (4)	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User entered '0'	System	29 Jan 2021 21:21:36



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56
User entered '1'	System	29 Jan 2021 21:21:36

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:43:56

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41

US3062151

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:08:57
User coded data point as SOC: Psychiatric disorders, HLT: Deliria (incl confusion), HLT: Confusion and disorientation, PT: Confusional state, LLT: Confusion - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 20:47:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 20:47:46
Data point term sent to Coder	System	02 Mar 2021 20:47:23
User entered 'CONFUSION'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:12
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:17
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:20
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:22
User entered '24 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:25
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User entered empty.	System	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:28
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:31
User entered '28 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:37
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User entered empty.	System	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:43
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:45
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:48
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:18:50
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:55
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:57
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:59
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:01
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:04
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:06
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:09
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:12
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:16
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:18
User entered 'Not Applicable (NOT APPLICABLE)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:19:21
User entered 'l'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (23)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:24
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

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**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:28
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:33
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

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**Folder: Adverse Events**

**Form: Adverse Events (23)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:19:36
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User entered '0'	System	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41
User entered '1'	System	02 Mar 2021 20:46:54

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:41

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**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 17:12:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 20:48:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 20:48:24
User entered 'WEAKNESS'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:41
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:43
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (25)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:45
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

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**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:51
User entered '22 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:54
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

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**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User entered empty.	System	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:56
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

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**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:58
User entered '28 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:00
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User entered empty.	System	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:06
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:08
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

US3062151

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:04:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:11
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:13
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:15
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:18
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:17:21
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42
	(b) (4)	

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Generated On: 09 Jun 2021 15:04:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:24
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:28
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:30
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:32
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:35
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:38
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:40
User entered 'Not Applicable (NOT APPLICABLE)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:43
User entered 'l'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:46
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:49
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

US3062151

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 15:04:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:55
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:17:58
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User entered '0'	System	02 Mar 2021 20:47:42



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00
User entered '1'	System	02 Mar 2021 20:47:42

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:46:00

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:17:08
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 20:49:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 20:49:46
Data point term sent to Coder	System	02 Mar 2021 20:49:25
User entered 'SYNCOPE EPISODE'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:14:11
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:14:13
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:14:16
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:14:49
User entered '27 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:14:51
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User entered empty.	System	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:06
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:07:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
User closed query 'Per DM CLR: Please review and verify the end date of this AE as it is unexpected to last for more than 1 day. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 08:52:47
Query 'Per DM CLR: Please review and verify the end date of this AE as it is unexpected to last for more than 1 day. Review and update eCRF as appropriate. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	11 Mar 2021 19:38:29
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	11 Mar 2021 19:38:21
User entered '27 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	11 Mar 2021 19:38:21
User opened query 'Per DM CLR: Please review and verify the end date of this AE as it is unexpected to last for more than 1 day. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:47
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 20:49:43
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 20:49:43
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 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:49
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User entered empty.	System	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45



US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:53
User entered 'No (N)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:56
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:59
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45
	(b) (4)	

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:02
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:04
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:09
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:06
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:11
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45



US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:14
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:18
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:19
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:22
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:25
User entered 'Not Related (NOT RELATED)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:16:28
User entered 'Not Applicable (NOT APPLICABLE)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:26
User entered 'I'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:29
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45



**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:31
User entered '0'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

US3062151

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Janna Martinez (b) (4)	02 Mar 2021 20:49:43
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Janna Martinez (b) (4)	02 Mar 2021 20:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 15:04:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:36
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:59:40
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:15:39
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User entered '0'	System	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40
User entered '1'	System	02 Mar 2021 20:48:45

**US3062151**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:10:40

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:04:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'please verify nicotine patch 21mg on 28Oct per hosp record' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:40:48
User closed query 'please verify sodium biphosphate enema 10/25-10/28 per hosp record' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:40:38
Query 'please verify sodium biphosphate enema 10/25-10/28 per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 20:04:41
	(b) (4)	
Query 'please verify nicotine patch 21mg on 28Oct per hosp record' answered with 'subject received nicotine patch on 10/28/2020, nicotine patch then discontinued on 10/28/2020. Recorded in source and EDC as such. ' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 20:00:26
	(b) (4)	
Query 'please verify albuterol-ipratropium 2.5mg breathing treatments per hosp record 10/21-10/28' canceled (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:12:39
User opened query 'please verify sodium biphosphate enema 10/25-10/28 per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:54:06
User opened query 'please verify nicotine patch 21mg on 28Oct per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:47:26
User opened query 'please verify albuterol-ipratropium 2.5mg breathing treatments per hosp record 10/21-10/28' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:40:11
User closed query 'please verify use of tramadol (ultram) 50mg PO q 8hr prn per hosp record' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:46:34
Query 'please verify use of tramadol (ultram) 50mg PO q 8hr prn per hosp record' answered with 'Tramadol was ordered but not given to subject' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:19:26
User opened query 'please verify use of tramadol (ultram) 50mg PO q 8hr prn per hosp record' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:23:27
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:35:56



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:04:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:13:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 17:15:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 17:15:18
Data point term sent to Coder	System	09 Aug 2020 01:16:36
Data point term sent to Coder	System	09 Aug 2020 01:14:36
User entered 'TREXAR- DIETARY SUPPLEMENT'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'OSTEOARTHRITIS, BILATERAL HIPS AND KNEES' reason for change: Data Entry Error	Janna Martinez (b) (4)	09 Aug 2020 01:15:43
	(b) (4)	
User entered 'NUTRITIONAL SUPPLEMENT'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'I'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'tablet (TABLET)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'once daily (QD)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:56:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	09 Aug 2020 01:14:38
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 01:14:21
User entered 'UN Jul 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:14:21
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 01:14:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 01:14:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 01:14:21

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: TONICS, ATC: TONICS, PRODUCT: DIETARY SUPPLEMENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:08:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:08:19
Data point term sent to Coder	System	09 Aug 2020 01:18:48
User entered 'CIRCU-DEFENSE DIETARY SUPPLEMENT'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 07:52:32
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	14 Sep 2020 19:09:48
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	14 Sep 2020 19:09:42
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	14 Sep 2020 19:09:42
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:25:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'NUTRITIONAL SUPPLEMENT'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'I'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'tablet (TABLET)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'once daily (QD)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:56:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	09 Aug 2020 01:17:48
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 01:17:43
User entered 'UN Feb 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:17:43
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 01:17:43

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 01:17:43

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 01:17:43

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: OTHER UROLOGICALS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 07:45:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 07:45:43
Data point term sent to Coder	System	10 Sep 2020 01:07:04
Coding entries removed.	marissa Mueller (b) (4)	10 Sep 2020 01:06:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: CRATEVA MAGNA;EQUISETUM ARVENSE;LINDERA AGGREGATA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 15:52:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 15:52:21
Data point term sent to Coder	System	09 Aug 2020 01:19:49
User entered 'URIVARX'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User closed query 'Per DM CLR: Please review and update the include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH entry, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:23:32
Query 'Per DM CLR: Please review and update the include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH entry, if applicable.' answered with 'udpated' (Site from DM).	marissa Mueller (b) (4)	10 Sep 2020 01:06:31
	(b) (4)	
User entered 'INCONTINENCE, urinary' reason for change: Data Entry Error	marissa Mueller (b) (4)	10 Sep 2020 01:06:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:59
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User opened query 'Per DM CLR: Please review and update the include the underlying type of Incontinence (Fecal, urinary, mixed). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH entry, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Sep 2020 15:37:21
User entered 'INCONTINENCE'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'I'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'tablet (TABLET)'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'once daily (QD)'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:56:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	09 Aug 2020 01:19:22
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 01:19:18
User entered 'UN Jul 2020'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
	Janna Martinez (b) (4)	
User entered 'Yes (Y)'	(b) (4)	09 Aug 2020 01:19:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:25:36
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:19:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User entered '1'	System	09 Aug 2020 01:19:18

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User entered '1'	System	09 Aug 2020 01:19:18

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:03
User entered '804 (804)'	System	09 Aug 2020 01:19:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 07:20:25
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 Aug 2020 07:20:25
Data point term sent to Coder	System	09 Aug 2020 01:21:00
User entered 'CELECOXIB'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'OSTEOARTHRITIS BILATERAL HIPS AND KNEES'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered '200'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'mg (mg)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'once daily (QD)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 10:56:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	09 Aug 2020 01:21:48
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 01:20:42
User entered 'UN UNK 2019'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered '0'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:26:06
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:26:08
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 21:44:21
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered empty.	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 16:36:57
User entered 'No (N)'	Janna Martinez (b) (4)	09 Aug 2020 01:20:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User entered '1'	System	09 Aug 2020 01:20:42

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User entered '1'	System	09 Aug 2020 01:20:42



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:10
User entered '804 (804)'	System	09 Aug 2020 01:20:42

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 13:45:30
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:45:30
Data point term sent to Coder	System	24 Mar 2021 14:26:03
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:05
DataPoint Un-verified.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
Coding entries removed.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
User entered 'HYDROCODONE/ACETAMINOPHEN 5mg/325mg' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
User closed query 'Per DM CLR: this Con Med was added on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:38:48
Query 'Per DM CLR: this Con Med was added on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'normal progression of disease' (Site from DM).	marissa Mueller (b) (4) (b) (4)	12 Nov 2020 15:42:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
User opened query 'Per DM CLR: this Con Med was added on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 03:18:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:49:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	02 Oct 2020 21:49:51
Data point term sent to Coder User entered	System Janna Martinez (b) (4)	02 Oct 2020 21:48:41 02 Oct 2020 21:47:49
'HYDROCODONE/ACETAMINOPHEN'	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 21:47:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 21:47:54
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	02 Oct 2020 21:47:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 21:47:49
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'OSTEOARTHRITIS, BILATERAL KNEES'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
	(b) (4)	
User entered '5/325'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
Un-reviewed for Data Management.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
DataPoint Un-verified.	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4) Colton King (b) (4)	24 Mar 2021 14:25:05
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'mg (mg)'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'as needed (PRN)'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '01 Sep 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '0'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Un-reviewed for Data Management.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:25:05
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'No (N)'	Janna Martinez (b) (4)	02 Oct 2020 21:47:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User entered empty.	System	02 Oct 2020 21:47:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User entered empty.	System	02 Oct 2020 21:47:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:14
User entered empty.	System	02 Oct 2020 21:47:49

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:50:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 21:49:42
User entered 'INFLUENZA VACCINE'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'INFLUENZA PROPHYLAXIS'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '0.5'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'mL (mL)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'once (ONCE)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'Intramuscular (INTRAMUSCULAR)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered empty.	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '26 Sep 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '0'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'No (N)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'please update end date on CM log' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:47:06
Query 'please update end date on CM log' answered with 'corrected' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:08:48
User opened query 'please update end date on CM log' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:09:24
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered '26 Sep 2020'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:12:39
User entered 'No (N)'	Janna Martinez (b) (4)	02 Oct 2020 21:49:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User entered empty.	System	02 Oct 2020 21:49:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User entered empty.	System	02 Oct 2020 21:49:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:18
User entered empty.	System	02 Oct 2020 21:49:07

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
Reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:10:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:10:45
Data point term sent to Coder	System	29 Oct 2020 21:10:15
User entered 'vitamin C'	marissa Mueller (b) (4) (b) (4)	29 Oct 2020 21:09:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'nutritional supplement'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '500'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'once daily (QD)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:19
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User entered 'I'	System	29 Oct 2020 21:09:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User entered 'I'	System	29 Oct 2020 21:09:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 23:59:30
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:22
User entered '804 (804)'	System	29 Oct 2020 21:09:19



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:58:55
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:58:55
Data point term sent to Coder	System	29 Oct 2020 21:10:15
User entered 'hydrocodone/acetaminophen (7.5mg/325mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'post op pain'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'I'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:51:12
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. ' answered with 'reconciled' (Site from DM).	Riley King (b) (4)	26 Feb 2021 15:46:59
Un-reviewed for Data Management.	Riley King (b) (4)	26 Feb 2021 15:46:50
DataPoint Un-verified.	Riley King (b) (4)	26 Feb 2021 15:46:50
User entered '24 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 15:46:50
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. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:55:23
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:44:58
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:44:58
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:44:58
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020' reason for change: New Information	Riley King (b) (4)	26 Feb 2021 15:46:50
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:44:58
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:44:58
User entered '20 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:44:58
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:09:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User entered empty.	System	29 Oct 2020 21:09:58



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User entered empty.	System	29 Oct 2020 21:09:58

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:41
User entered empty.	System	29 Oct 2020 21:09:58

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 05:57:02
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 05:57:02
Data point term sent to Coder	System	29 Oct 2020 21:11:18
User entered 'Zofran'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:41
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:44
User entered 'post op nausea'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:46
User entered '4'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:48
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:51
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:53
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:53:56
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:00
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:02
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:08:10
Un-reviewed for Data Management.	Jeri King (b) (4)	25 Nov 2020 23:25:59
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:25:59
User entered '14 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:25:59
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:04
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:07
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:46:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:56:53
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	26 Feb 2021 15:49:01
Un-reviewed for Data Management.	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Riley King (b) (4)	26 Feb 2021 15:48:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 14:58:55
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:04:45
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:09
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Un-reviewed for Data Management.	Riley King (b) (4)	26 Feb 2021 15:48:39
User entered '30 Oct 2020' reason for change: Per Query Resolution	Riley King (b) (4)	26 Feb 2021 15:48:39
DataPoint Un-verified.	(b) (4), (b) (6)	16 Feb 2021 14:59:03
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:12
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:14
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:11:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User entered empty.	System	29 Oct 2020 21:11:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User entered empty.	System	29 Oct 2020 21:11:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:45
User entered empty.	System	29 Oct 2020 21:11:13

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
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)	30 Oct 2020 05:29:53
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 05:29:53
Data point term sent to Coder	System	29 Oct 2020 21:15:29
User entered 'pantoprazole'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'post op nausea'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '40'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'once daily (QD)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:27:07
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:27:05
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
User entered '20 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:46:09
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:13
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User entered '1'	System	29 Oct 2020 21:15:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User entered '1'	System	29 Oct 2020 21:15:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:51
User entered '804 (804)'	System	29 Oct 2020 21:15:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:16:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:16:47
Data point term sent to Coder	System	29 Oct 2020 21:16:31
User entered 'sertraline'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
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)	22 Dec 2020 07:59:41
User closed query 'Depression is not listed in MH section under screening tab-please reconcile' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 21:32:22
Query 'Depression is not listed in MH section under screening tab-please reconcile' answered with 'Condition added to MH under screening tab.' (Site from CRA).	Sherry Henning (b) (4) (b) (4)	17 Dec 2020 21:03:28
User opened query 'Depression is not listed in MH section under screening tab-please reconcile' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:56:26
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 'Depression added to medical history ' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 20:12:52
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)	04 Dec 2020 08:37:43
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'depression'	marissa Mueller (b) (4) (b) (4)	29 Oct 2020 21:15:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '50'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'once daily (QD)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:45:35
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:45:35
	(b) (4)	
User entered '22 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:45:35
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '28 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:15:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:15:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:15:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 21:15:51



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 08:49:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 08:49:52
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 22:30:30
Coding entries removed.	Riley King (b) (4)	04 Feb 2021 22:30:21
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 23:36:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 23:36:56
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 21:16:32
User entered 'baclofen'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:39:31
User closed query 'please verify location' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:39:28
Query 'please verify location' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:30:29
Un-reviewed for Data Management.	(b) (4)	
	Riley King (b) (4)	04 Feb 2021 22:30:21
User entered 'POST Operative pain PAIN, generalized' reason for change: Per Query Resolution	(b) (4)	04 Feb 2021 22:30:21
User opened query 'please verify location' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:30:56
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:30:34
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'post op pain'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '10'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:16
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:16:16



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:16:16

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:16:16

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:10:53
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 08:10:53
Data point term sent to Coder	System	11 Mar 2021 19:48:18
Coding entries removed.	Riley King (b) (4)	11 Mar 2021 19:47:31
Reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:17:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:17:56
Data point term sent to Coder	System	29 Oct 2020 21:17:32
User entered 'hydroxyzine'	marissa Mueller (b) (4) (b) (4)	29 Oct 2020 21:16:40

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 22:01:25
User closed query 'please note indication is for pain per hosp record' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 22:01:22
Query 'please note indication is for pain per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 19:47:42
Un-reviewed for Data Management.	(b) (4)	
	Riley King (b) (4)	11 Mar 2021 19:47:31
	(b) (4)	
User entered 'abdominal pain' reason for change:	Riley King (b) (4)	11 Mar 2021 19:47:31
Data Entry Error	(b) (4)	
User opened query 'please note indication is for pain per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:55:35
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 18:55:02
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)	22 Dec 2020 07:59:07
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 'anxiety added to medical history' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 20:13:27
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)	04 Dec 2020 08:37:08
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'anxiety'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '25'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '20 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Un-reviewed for Data Management.	Riley King (b) (4)	11 Mar 2021 19:47:31
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	11 Mar 2021 19:47:31
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	11 Mar 2021 19:47:31
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Un-reviewed for Data Management.	Riley King (b) (4)	11 Mar 2021 19:47:31
DataPoint Un-verified.	Riley King (b) (4)	11 Mar 2021 19:47:31
User entered '28 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	11 Mar 2021 19:47:31
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:16:40
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User entered empty.	System	29 Oct 2020 21:16:40

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User entered empty.	System	29 Oct 2020 21:16:40

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:59:59
User entered empty.	System	29 Oct 2020 21:16:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:19:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:19:50
Data point term sent to Coder	System	29 Oct 2020 21:17:32
User entered 'ceftriaxone'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'post op wound infection'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '2'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'g (g)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'once daily (QD)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '28 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered '0'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:28:58
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Query 'please verify as 28Oct2020 as per CM log' canceled (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:43:26
User opened query 'please verify as 28Oct2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:23:24
Un-reviewed for Data Management.	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
User entered '7 Jan 2021' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:46:39
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
	(b) (4), (b) (6)	
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Data Management.	(b) (4), (b) (6)	09 Nov 2020 03:18:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:33
User entered 'No (N)'	marissa Mueller (b) (4)	29 Oct 2020 21:17:31
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User entered '1'	System	29 Oct 2020 21:17:31

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User entered '1'	System	29 Oct 2020 21:17:31

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:04
User entered '804 (804)'	System	29 Oct 2020 21:17:31

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:19:53
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:06:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 23:07:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 23:07:25
Data point term sent to Coder	System	25 Nov 2020 23:06:39
User entered 'Hydroxyzine'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:30
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:19:55
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:06:09



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:32
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:19:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Anxiety'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:35
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:46
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '25'	Jeri King (b) (4)	25 Nov 2020 23:06:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:42
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:50
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:06:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:39
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:54
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'as needed (PRN)'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:44
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:46
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:20:58
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:48
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:21:01
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:06:09



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:50
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #13 HYDROXYZINE (20 OCT 2020 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:08:52
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #13 HYDROXYZINE (20 OCT 2020 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'This medication was only taken on 10/15/2020. ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 22:38:47
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:38:26
User entered '15 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 22:38:26
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #13 HYDROXYZINE (20 OCT 2020 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:29:35
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '20 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:06:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:53
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:38:26
User entered 'No (N)' reason for change: Per Query Resolution	Riley King (b) (4)	29 Jan 2021 22:38:26
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:06:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:31:55
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 22:38:26
User entered '15 Oct 2020' reason for change: Per Query Resolution	Riley King (b) (4)	29 Jan 2021 22:38:26
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User entered empty.	System	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User entered empty.	System	25 Nov 2020 23:06:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:12
User entered empty.	System	25 Nov 2020 23:06:09



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 21:59:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:59:23
Data point term sent to Coder	System	29 Jan 2021 21:53:43
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 21:53:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:05:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:39:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:39:04
Data point term sent to Coder	System	25 Nov 2020 23:07:40
User entered 'Ceftriaxone'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:46:03
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:53:29
User entered 'POSTOPERATIVE WOUND INFECTION, left hip' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 21:53:29
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Postoperative Wound Infection'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '2'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'g (g)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once daily (QD)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:08



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
DataPoint Un-verified.	Riley King (b) (4)	04 Feb 2021 22:36:02
User entered '27 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	04 Feb 2021 22:36:02
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '28 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:46:16
User closed query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:09:44
Query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' answered with 'Reconciled ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 21:54:41
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:54:21
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:54:21
User opened query 'Per DM CLR: Please review and verify if this medication is ongoing as this is not the standard duration of treatment for this medication. Either update the Stop Date or provide explanation for continued use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:29:58
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:46:12
User closed query 'please verify as 28Oct2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:46:08
Query 'please verify as 28Oct2020 as per CM log' answered with 'reconciled' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:36:10
User entered '28 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
	Riley King (b) (4)	04 Feb 2021 22:36:02
User opened query 'please verify as 28Oct2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:25:03
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:54:21
	(b) (4)	
User entered '7 Jan 2021' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:54:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User entered '1'	System	25 Nov 2020 23:07:08



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User entered '1'	System	25 Nov 2020 23:07:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:15
User entered '804 (804)'	System	25 Nov 2020 23:07:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:05:29
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.	Coder Import (b) (4)	25 Nov 2020 23:10:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 23:08:41
User entered 'Lactated Ringers'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:07:52

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '850'	Jeri King (b) (4)	25 Nov 2020 23:07:52

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mL (mL)'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:52



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:08:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 23:08:38
User entered 'once (ONCE)' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:08:38
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:07:52
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:07:52



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User entered empty.	System	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User entered empty.	System	25 Nov 2020 23:07:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:18
User entered empty.	System	25 Nov 2020 23:07:52

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
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 17:06:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:06:54
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:13:05
User closed query 'please correct spelling to saline' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 20:13:02
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)	15 Dec 2020 20:16:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 20:16:37
Data point term sent to Coder	System	15 Dec 2020 20:15:04
Query 'please correct spelling to saline' answered with 'corrected' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:14:26
Coding entries removed.	Jeri King (b) (4)	15 Dec 2020 20:14:20
User entered 'NORMAL SALINE' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 20:14:20
User opened query 'please correct spelling to saline' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:05:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:04:29

[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: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 09:54:10
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 09:54:10
Data point term sent to Coder	System	25 Nov 2020 23:10:43
User entered 'Normal Salin'	Jeri King (b) (4) (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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 Feb 2021 12:23:55
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.	Riley King (b) (4)	29 Jan 2021 21:56:03
' answered with 'Subject received medication prior to, during, and following a hip replacement surgery to correct AE. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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)	13 Jan 2021 09:30:17
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:09:46



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '125'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mL (mL)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'other (OTHER)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Every hour'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:09:46



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User entered empty.	System	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User entered empty.	System	25 Nov 2020 23:09:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:22
User entered empty.	System	25 Nov 2020 23:09:46

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
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)	8 Apr 2021 17:06:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:06:54
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:04:40
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)	26 Nov 2020 09:54:10
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 09:54:10
Data point term sent to Coder	System	25 Nov 2020 23:10:43
User entered 'Normal Saline'	Jeri King (b) (4) (b) (4)	25 Nov 2020 23:10:41



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:10:41

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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 Feb 2021 12:24:06
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.	Riley King (b) (4)	29 Jan 2021 21:56:56
' answered with 'Subject received medication prior to, during, and following hip replacement surgery to correct AE. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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)	13 Jan 2021 09:30:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '70'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mL (mL)'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'other (OTHER)'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Every hour'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:10:41



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:10:41

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User entered empty.	System	25 Nov 2020 23:10:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User entered empty.	System	25 Nov 2020 23:10:41



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:31
User entered empty.	System	25 Nov 2020 23:10:41

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFAZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 11:57:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	18 Dec 2020 11:57:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:13:20
User closed query 'please enter as cefozolin ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 20:13:19
Data point term sent to Coder	System	15 Dec 2020 20:17:06
Query 'please enter as cefozolin ' answered with 'corrected' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:16:17
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	15 Dec 2020 20:16:10
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'corrected' (Site from System).	Jeri King (b) (4)	15 Dec 2020 20:16:10
Data point term sent to Coder	System	15 Dec 2020 20:16:05
User entered 'ANCEF (cefazolin)' reason for change: Data Entry Error	Jeri King (b) (4)	15 Dec 2020 20:15:59
User opened query 'please enter as cefozolin ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:16:49
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 Nov 2020 06:38:02
Data point term sent to Coder	System	25 Nov 2020 23:11:46
User entered 'Ancef'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'I'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'g (g)'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:11:38

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'other (OTHER)'	Jeri King (b) (4)	25 Nov 2020 23:11:38



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User closed query 'Per CDM: Please note that "three times daily" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:49:54
Query 'Per CDM: Please note that "three times daily" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' answered with 'Three times daily is not the same as Q8hours. Q8 hours is Correct' (Site from DM).	Jeri King (b) (4)	15 Dec 2020 20:16:41
User opened query 'Per CDM: Please note that "three times daily" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:46:55
User entered 'Every 8 hours'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:11:38



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User entered empty.	System	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User entered empty.	System	25 Nov 2020 23:11:38

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:35
User entered empty.	System	25 Nov 2020 23:11:38

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	03 Feb 2021 17:33:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 13:05:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	03 Feb 2021 13:05:43
User closed query 'Per DM CLR: Please provide the concentration of this medication in the medication name as there are multiple dosage options available. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:11:57
Query 'Per DM CLR: Please provide the concentration of this medication in the medication name as there are multiple dosage options available. Review and amend as appropriate. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 21:57:49
Data point term sent to Coder	System	29 Jan 2021 21:57:46
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:57:40
Coding entries removed.	(b) (4)	29 Jan 2021 21:57:40
User entered 'TRANEXAMIC ACID 1000mg/mL' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:57:40
User opened query 'Per DM CLR: Please provide the concentration of this medication in the medication name as there are multiple dosage options available. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:31:31
User closed query 'please provide source in hosp record' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 20:14:42

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'please provide source in hosp record' answered with 'On medication record' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:17:13
User opened query 'please provide source in hosp record' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:33:02
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:02:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:43:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:43:04
Data point term sent to Coder	System	25 Nov 2020 23:12:47
User entered 'Tranexamic Acid'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:56:39
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	26 Feb 2021 15:51:33
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:56:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '10'	Jeri King (b) (4)	25 Nov 2020 23:12:22



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mL (mL)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Intravenous (INTRAVENOUS)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:12:22



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:12:22

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User entered empty.	System	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User entered empty.	System	25 Nov 2020 23:12:22

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:40
User entered empty.	System	25 Nov 2020 23:12:22

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:02:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:43:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:43:04
Data point term sent to Coder	System	25 Nov 2020 23:13:48
User entered 'Tranexamic Acid'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:07



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:13:07

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '10'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mL (mL)'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:07

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:24:43
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Per medical records subject administered this medication topically. ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 21:58:40
	(b) (4)	
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:31:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Topical (TOPICAL)'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:07



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User entered empty.	System	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User entered empty.	System	25 Nov 2020 23:13:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:43
User entered empty.	System	25 Nov 2020 23:13:07



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:02:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:17:11
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:17:11
Data point term sent to Coder	System	25 Nov 2020 23:14:50
User entered 'Hydroxyzine'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Postoperative Nausea recurrent'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '25'	Jeri King (b) (4)	25 Nov 2020 23:13:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'as needed (PRN)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:51



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Nov 2020 23:14:11
User entered '15 Oct 2020' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:14:11
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Nov 2020 23:13:51
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User entered empty.	System	25 Nov 2020 23:13:51



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User entered empty.	System	25 Nov 2020 23:13:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:47
User entered empty.	System	25 Nov 2020 23:13:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:23:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:23:45
Data point term sent to Coder	System	29 Jan 2021 21:59:48
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 21:59:07
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:01:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:11:05
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:11:05
Data point term sent to Coder	System	25 Nov 2020 23:15:51
User entered 'Oxycodone/Acetaminophen (10mg/325mg)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:20:23
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 21:59:18
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 21:59:07
User entered 'POSTOPERATIVE PAIN, generalized' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:32:08
DataPoint Verified.	Stephan Penn (b) (4)	17 Dec 2020 20:14:05
User entered 'Postoperative Pain'	(b) (4)	
	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'I'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'tablet (TABLET)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:15:21



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'as needed (PRN)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '19 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:15:21



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User entered empty.	System	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User entered empty.	System	25 Nov 2020 23:15:21

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:55
User entered empty.	System	25 Nov 2020 23:15:21

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:31:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:31:43
Data point term sent to Coder	System	29 Jan 2021 22:00:51
Coding entries removed.	Riley King (b) (4)	29 Jan 2021 22:00:23
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:01:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:58:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:58:20
Data point term sent to Coder	System	25 Nov 2020 23:16:51
User entered 'Scopolamine'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '1.5'	Jeri King (b) (4)	25 Nov 2020 23:16:25



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'as needed (PRN)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:16:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:22:29
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:36:24
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 22:00:32
DataPoint Un-verified.	(b) (4)	
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 22:00:23
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:32:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:16:25



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User entered empty.	System	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User entered empty.	System	25 Nov 2020 23:16:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:59
User entered empty.	System	25 Nov 2020 23:16:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:01:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:48:03
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:48:03
Data point term sent to Coder	System	25 Nov 2020 23:17:52
User entered 'Celebrex'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:17:04



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Osteoarthritis Bilateral Hips'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '100'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'twice daily (BID)'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:17:04



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 CELECOXIB (UN UNK 2019-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 CELECOXIB (UN UNK 2019-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'Conmed #4 ended 10/13/2020. No overlap of this med and conmed #4 took place. ' (Site from DM).	Riley King (b) (4)	29 Jan 2021 21:48:55
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #4 CELECOXIB (UN UNK 2019-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:33:11
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:17:04

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:47:34
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:47:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:17:04

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:47:34
User entered '20 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:47:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User entered '2'	System	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User entered '1'	System	25 Nov 2020 23:17:04

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:02
User entered '804 (804)'	System	25 Nov 2020 23:17:04



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:00:42
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 TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:39:06
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:39:06
Data point term sent to Coder	System	25 Nov 2020 23:18:52
User entered 'Toradol'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '10'	Jeri King (b) (4)	25 Nov 2020 23:18:29

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:18:29



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:18:29

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User entered empty.	System	25 Nov 2020 23:18:29



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User entered empty.	System	25 Nov 2020 23:18:29

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:06
User entered empty.	System	25 Nov 2020 23:18:29

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:00:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:57:02
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:57:02
Data point term sent to Coder	System	25 Nov 2020 23:19:53
User entered 'Dexamethasone'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '4'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:19:46



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:19:46



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User entered empty.	System	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User entered empty.	System	25 Nov 2020 23:19:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:17
User entered empty.	System	25 Nov 2020 23:19:46

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 18:00:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:21:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:21:57
Data point term sent to Coder	System	25 Nov 2020 23:20:54
User entered 'Tylenol'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '650'	Jeri King (b) (4)	25 Nov 2020 23:20:30



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:20:30

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'as needed (PRN)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:20:30



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User entered empty.	System	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User entered empty.	System	25 Nov 2020 23:20:30

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:19
User entered empty.	System	25 Nov 2020 23:20:30

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:59:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:11:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 08:11:04
Data point term sent to Coder	System	25 Nov 2020 23:21:56
User entered 'Oxycodone/Acetaminophen (5mg/325mg)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:21:19



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hips Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'l'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'tablet (TABLET)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:19



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:21:19

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User entered empty.	System	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User entered empty.	System	25 Nov 2020 23:21:19

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:23
User entered empty.	System	25 Nov 2020 23:21:19



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:59:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:39:03
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 06:39:03
Data point term sent to Coder	System	25 Nov 2020 23:21:56
User entered 'Aspirin'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Osteoarthritis bilateral Hips'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '325'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once daily (QD)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:55



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:21:55

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:49:44
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:49:44
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
DataPoint Un-verified.	Riley King (b) (4)	29 Jan 2021 21:49:44
User entered '22 Oct 2020' reason for change: New Information	Riley King (b) (4)	29 Jan 2021 21:49:44
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User entered '1'	System	25 Nov 2020 23:21:55



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User entered '1'	System	25 Nov 2020 23:21:55

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:27
User entered '804 (804)'	System	25 Nov 2020 23:21:55

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:59:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 23:24:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 23:22:57
User entered 'Docusate Sodium'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Constipation'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '100'	Jeri King (b) (4)	25 Nov 2020 23:22:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:22:25



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'twice daily (BID)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:21:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:21:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:21:58
	(b) (4)	
User entered '15 Jan 2021' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:21:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:22:25



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '2'	System	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '1'	System	25 Nov 2020 23:22:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '804 (804)'	System	25 Nov 2020 23:22:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 17:58:09
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 10:05:11
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	26 Nov 2020 10:05:11
Data point term sent to Coder	System	25 Nov 2020 23:23:57
User entered 'Pepcid'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 17:58:11
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Postoperative Nausea'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '20'	Jeri King (b) (4)	25 Nov 2020 23:23:13



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'twice daily (BID)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:23:13



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '15 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User entered '2'	System	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User entered '1'	System	25 Nov 2020 23:23:13

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:34
User entered '804 (804)'	System	25 Nov 2020 23:23:13

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE HYDROCHLORIDE;EPINEPHRINE, PRODUCTSYNONYM: MARCAINE W/EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:39:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:39:33
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
Data point term sent to Coder	System	16 Mar 2021 15:33:34
User closed query 'please enter each med on a separate line' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 14:42:43
Data point term sent to Coder	System	29 Jan 2021 22:37:08
User closed query 'For coding purposes, this entry references 6 medications that while given together, must be reported separately as the combined ingredients are not referenced together in the standard coding dictionary. Please split and report separately (one drug per line) to capture coding for all the terms.' (Site from System).	System	29 Jan 2021 22:37:03
Query 'For coding purposes, this entry references 6 medications that while given together, must be reported separately as the combined ingredients are not referenced together in the standard coding dictionary. Please split and report separately (one drug per line) to capture coding for all the terms.' answered with 'Correct as entered- joint cocktail. ' (Site from System).	Riley King (b) (4) (b) (4)	29 Jan 2021 22:37:03
User opened query 'For coding purposes, this entry references 6 medications that while given together, must be reported separately as the combined ingredients are not referenced together in the standard coding dictionary. Please split and report separately (one drug per line) to capture coding for all the terms.' (Site from System).	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:54:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	30 Dec 2020 23:52:30
Query 'For coding purposes, this entry references o events 6 medications that while given together, must be reported separately as the combined ingredients are not referenced together in the standard coding dictionary. Please split and report separately (one drug per line) to capture coding for all the terms.' canceled (Site from System).	Coder Import (b) (4)	30 Dec 2020 23:52:23
User opened query 'For coding purposes, this entry references o events 6 medications that while given together, must be reported separately as the combined ingredients are not referenced together in the standard coding dictionary. Please split and report separately (one drug per line) to capture coding for all the terms.' (Site from System).	Coder Import (b) (4)	30 Dec 2020 23:50:23
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
Query 'please enter each med on a separate line' answered with 'There is not a trade name. This is a mixed solution given together.' (Site from CRA).	Jeri King (b) (4)	15 Dec 2020 20:18:11
Data point term sent to Coder	System	15 Dec 2020 20:18:07
User closed query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	System	15 Dec 2020 20:18:06
Query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' answered with 'There is not a trade name. This is a mixed solution given together.' (Site from System).	Jeri King (b) (4)	15 Dec 2020 20:18:06
User opened query 'please enter each med on a separate line' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 18:20:46
User opened query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	Coder Import (b) (4)	27 Nov 2020 18:32:11
Data point term sent to Coder	System	25 Nov 2020 23:25:57



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'morphine 10mg, dexamethasone 8mg, toradol 60mg, Epinephrine 1:1000 0.25ml, Marcaine 0.25% 30ml, Normal Saline 30 ml'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Left Hip Osteoarthritis'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'I'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Other (OTHER)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'unit'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'once (ONCE)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:25:37



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:40:29
DataPoint Un-verified.	Riley King (b) (4)	16 Mar 2021 15:32:57
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	16 Mar 2021 15:32:57
reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please review the	(b) (4), (b) (6)	21 Feb 2021 12:25:30
Route as this medication is not typically administered		
as indicated. Please update route as appropriate.		
Otherwise, please provide clarification.		
' (Site from DM).		
Query 'Per DM CLR: Please review the Route as this	Riley King (b) (4)	29 Jan 2021 22:37:59
medication is not typically administered as indicated.	(b) (4)	
Please update route as appropriate. Otherwise, please		
provide clarification.		
' answered with 'Correct as entered' (Site from DM).		
User opened query 'Per DM CLR: Please review the	(b) (4), (b) (6)	13 Jan 2021 09:33:34
Route as this medication is not typically administered		
as indicated. Please update route as appropriate.		
Otherwise, please provide clarification.		
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered '14 Oct 2020'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:05
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User entered empty.	System	25 Nov 2020 23:25:37



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User entered empty.	System	25 Nov 2020 23:25:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:38
User entered empty.	System	25 Nov 2020 23:25:37

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:14
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 16:22:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 16:22:20
Data point term sent to Coder	System	29 Jan 2021 16:22:02
User entered 'Oxygen therapy'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:16
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:21:10
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
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 COPD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4)	
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 COPD should be recorded, and update con med indication or provide clarification. ' answered with 'Not worsening ' (Site from DM).	Riley King (b) (4)	26 Feb 2021 15:52:40
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 COPD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:55:37
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:18
User entered 'Chronic obstructive pulmonary disease'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:20
User entered 'I'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:23
User entered 'Other (OTHER)'	Riley King (b) (4)	29 Jan 2021 16:21:10

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:26
User entered 'liter per minute'	Riley King (b) (4)	29 Jan 2021 16:21:10
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:28
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:30
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:32
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:34
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:21:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:36
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:38
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:40
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:42
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:21:10
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User entered empty.	System	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User entered empty.	System	29 Jan 2021 16:21:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:43
User entered empty.	System	29 Jan 2021 16:21:10

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:39:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 23:45:34
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 23:45:34
Data point term sent to Coder	System	29 Jan 2021 16:23:03
User entered 'Fentanyl'	Riley King (b) (4)	29 Jan 2021 16:22:05

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '50'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:50:34
Query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' answered with 'reconciled' (Site from DM).	Riley King (b) (4)	26 Feb 2021 16:00:50
User entered 'ug (ug)' reason for change: Per Query Resolution	Riley King (b) (4)	26 Feb 2021 16:00:40
User opened query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'ug'. If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:51:12
User entered 'Other (OTHER)'	Riley King (b) (4)	29 Jan 2021 16:22:05

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty; reason for change Per Query Resolution	Riley King (b) (4)	26 Feb 2021 16:00:40
User entered 'MCG'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:22:05



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:22:05
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User entered empty.	System	29 Jan 2021 16:22:05

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User entered empty.	System	29 Jan 2021 16:22:05

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:46
User entered empty.	System	29 Jan 2021 16:22:05

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	30 Jan 2021 00:11:26
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:11:26
Data point term sent to Coder	System	29 Jan 2021 16:24:06
User entered 'Lidocaine 1%'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'I'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mL (mL)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '27 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:23:18
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User entered empty.	System	29 Jan 2021 16:23:18

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User entered empty.	System	29 Jan 2021 16:23:18

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:49
User entered empty.	System	29 Jan 2021 16:23:18



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:37:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:37:23
Data point term sent to Coder	System	29 Jan 2021 16:25:08
User entered 'Hydromorphone'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0.5'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:24:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User entered empty.	System	29 Jan 2021 16:24:12



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User entered empty.	System	29 Jan 2021 16:24:12

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:10
User entered empty.	System	29 Jan 2021 16:24:12

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:23:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:23:24
Data point term sent to Coder	System	29 Jan 2021 16:53:50
User entered 'Ceftriaxone'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection left hip'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '2000'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '27 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:53:36
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User entered '1'	System	29 Jan 2021 16:53:36

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User entered '1'	System	29 Jan 2021 16:53:36

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:11
User entered '804 (804)'	System	29 Jan 2021 16:53:36

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 16:58:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	29 Jan 2021 16:58:21
Data point term sent to Coder	System	29 Jan 2021 16:57:56
User entered 'Colace'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Constipation'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '100'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User entered empty.	System	29 Jan 2021 16:57:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User entered empty.	System	29 Jan 2021 16:57:51

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:15
User entered empty.	System	29 Jan 2021 16:57:51

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: RED BLOOD CELLS, CONCENTRATED - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 09:47:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:47:39
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:59
Data point term sent to Coder	System	29 Jan 2021 17:02:02
User entered 'Packed red blood cells'	Riley King (b) (4) (b) (4)	29 Jan 2021 17:01:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:01
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:03
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:05
User entered 'I'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:07
User entered 'Other (OTHER)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:11
User entered 'Unit'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:13
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:15
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:19
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:22
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:56
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:54
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:52
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:49
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:24
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:01:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User entered empty.	System	29 Jan 2021 17:01:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User entered empty.	System	29 Jan 2021 17:01:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:19
User entered empty.	System	29 Jan 2021 17:01:49



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:06:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:06:20
Data point term sent to Coder	System	29 Jan 2021 17:06:04
User entered 'Miralax'	Riley King (b) (4)	29 Jan 2021 17:05:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Constipation'	Riley King (b) (4)	29 Jan 2021 17:05:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '17'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'g (g)'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:05:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:05:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:05:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User entered empty.	System	29 Jan 2021 17:05:14



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User entered empty.	System	29 Jan 2021 17:05:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:56
User entered empty.	System	29 Jan 2021 17:05:14

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:08:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	29 Jan 2021 17:08:20
Data point term sent to Coder	System	29 Jan 2021 17:08:06
User entered 'Tylenol'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '650'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:17:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:17:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:17:40
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:17:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:07:45
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User entered empty.	System	29 Jan 2021 17:07:45

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User entered empty.	System	29 Jan 2021 17:07:45

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:02:59
User entered empty.	System	29 Jan 2021 17:07:45

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:11:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:11:23
Data point term sent to Coder	System	29 Jan 2021 17:11:15
User entered 'Norco'	Riley King (b) (4)	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative, generalized'	Riley King (b) (4)	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '5/325'	Riley King (b) (4)	29 Jan 2021 17:11:03



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:11:03

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:17:18
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:17:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:17:18
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:17:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:11:03
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User entered empty.	System	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User entered empty.	System	29 Jan 2021 17:11:03

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:03
User entered empty.	System	29 Jan 2021 17:11:03

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 08:05:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 08:05:54
Data point term sent to Coder	System	26 Feb 2021 16:04:02
Coding entries removed.	Riley King (b) (4)	26 Feb 2021 16:03:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	29 Jan 2021 17:13:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:13:21
Data point term sent to Coder	System	29 Jan 2021 17:13:16
User entered 'Ondansetron'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:12:34



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative nausea, recurrent' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 16:03:09
User entered 'Nausea'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '4'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:56:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	26 Feb 2021 16:03:16
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 16:03:09
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:55:51
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 17:12:34

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '30 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 16:03:09
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:12:34

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:12:34
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User entered empty.	System	29 Jan 2021 17:12:34

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User entered empty.	System	29 Jan 2021 17:12:34

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:07
User entered empty.	System	29 Jan 2021 17:12:34



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	01 Mar 2021 16:30:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 16:28:33
Coding entries removed.	Sherry Henning (b) (4)	01 Mar 2021 16:27:57
User entered 'Lactated ringers' reason for change:	(b) (4)	
Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 16:27:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: LOSARTAN POTASSIUM;RAMIPRIL, PRODUCTSYNONYM: LR - 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)	29 Jan 2021 17:14:21
Data point term sent to Coder	System	29 Jan 2021 17:14:17
User entered 'LR'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1000'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:13:59

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:13:59
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User entered empty.	System	29 Jan 2021 17:13:59



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User entered empty.	System	29 Jan 2021 17:13:59

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:10
User entered empty.	System	29 Jan 2021 17:13:59

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:27
Data point term sent to Coder	System	29 Jan 2021 17:15:18
User entered 'Propofol'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '500'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:15:02
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User entered empty.	System	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User entered empty.	System	29 Jan 2021 17:15:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:14
User entered empty.	System	29 Jan 2021 17:15:02

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:27
Data point term sent to Coder	System	29 Jan 2021 17:33:32
User entered 'Propofol'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '200'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:33:17
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User entered empty.	System	29 Jan 2021 17:33:17

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User entered empty.	System	29 Jan 2021 17:33:17

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:32
User entered empty.	System	29 Jan 2021 17:33:17

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:20:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:20:23
Data point term sent to Coder	System	29 Jan 2021 17:34:33
User entered 'Azithromycin'	Riley King (b) (4)	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '500'	Riley King (b) (4)	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:34:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:34:08

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:34:08



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:34:08
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User entered empty.	System	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User entered empty.	System	29 Jan 2021 17:34:08

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:43
User entered empty.	System	29 Jan 2021 17:34:08



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:36:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:36:20
Data point term sent to Coder	System	29 Jan 2021 17:35:34
User entered 'Dilaudid'	Riley King (b) (4)	29 Jan 2021 17:35:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0.5'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:35:14
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User entered empty.	System	29 Jan 2021 17:35:14



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User entered empty.	System	29 Jan 2021 17:35:14

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:49
User entered empty.	System	29 Jan 2021 17:35:14

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	29 Jan 2021 21:23:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:23:23
Data point term sent to Coder	System	29 Jan 2021 17:37:35
User entered 'Cefepime'	Riley King (b) (4)	29 Jan 2021 17:37:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '2'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'g (g)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:37:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User entered '1'	System	29 Jan 2021 17:37:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User entered '1'	System	29 Jan 2021 17:37:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:03:56
User entered '804 (804)'	System	29 Jan 2021 17:37:02

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	01 Feb 2021 15:42:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:42:29
Data point term sent to Coder	System	29 Jan 2021 17:38:36
User entered 'Vancomycin'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1500'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:02
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User entered empty.	System	29 Jan 2021 17:38:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User entered empty.	System	29 Jan 2021 17:38:02

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:02
User entered empty.	System	29 Jan 2021 17:38:02

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 13:49:28
Data point term sent to Coder	System	29 Jan 2021 17:39:36
User entered 'Propofol'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '60'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:38:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User entered empty.	System	29 Jan 2021 17:38:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User entered empty.	System	29 Jan 2021 17:38:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:08
User entered empty.	System	29 Jan 2021 17:38:47



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:55:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:40:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:40:29
Data point term sent to Coder	System	29 Jan 2021 17:41:38
User entered 'tobramycin'	Riley King (b) (4)	29 Jan 2021 17:41:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:55:34
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:55:39
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 17:41:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1.2'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'g (g)'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Topical (TOPICAL)'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:41:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:41:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User entered empty.	System	29 Jan 2021 17:41:01



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User entered empty.	System	29 Jan 2021 17:41:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:13
User entered empty.	System	29 Jan 2021 17:41:01

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	01 Feb 2021 15:42:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:42:29
Data point term sent to Coder	System	29 Jan 2021 17:42:39
User entered 'Vancomycin'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1000'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:42:10
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User entered '1'	System	29 Jan 2021 17:42:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User entered '1'	System	29 Jan 2021 17:42:10

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:17
User entered '804 (804)'	System	29 Jan 2021 17:42:10

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:41:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	01 Feb 2021 15:41:29
Data point term sent to Coder	System	29 Jan 2021 17:44:45
User entered 'Tranexamic acid'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1000'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'twice daily (BID)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Topical (TOPICAL)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:04:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:43:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User entered '2'	System	29 Jan 2021 17:43:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User entered '1'	System	29 Jan 2021 17:43:52

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:50
User entered '804 (804)'	System	29 Jan 2021 17:43:52

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 22:49:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 22:49:29
Data point term sent to Coder	System	29 Jan 2021 17:47:49
User entered 'Dexamethasone'	Riley King (b) (4)	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '5'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:47:11
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User entered empty.	System	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User entered empty.	System	29 Jan 2021 17:47:11

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:04:44
User entered empty.	System	29 Jan 2021 17:47:11



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:46:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:46:29
Data point term sent to Coder	System	29 Jan 2021 17:48:52
User entered 'Phenylephrine'	Riley King (b) (4)	29 Jan 2021 17:48:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Hypotension'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0.1'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:48:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:48:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:48:07
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:48:07



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:48:07

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:48:07

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 14:08:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 14:08:36
Data point term sent to Coder	System	29 Jan 2021 17:50:53
User entered 'Rocuronium'	Riley King (b) (4)	29 Jan 2021 17:49:56

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '50'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:49:56



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:04:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:49:56

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:49:56

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:49:56
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:49:56

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:49:56

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (62)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:49:56

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM, PRODUCTSYNONYM: SUCCINYLCHOLINE [SUXAMETHONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 16:06:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 16:06:44
Data point term sent to Coder	System	29 Jan 2021 17:50:53
User entered 'Succinylcholine'	Riley King (b) (4)	29 Jan 2021 17:50:48

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:50:48

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '100'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:50:48

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:50:48
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:50:48

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:50:48

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (63)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:05:36
User entered empty.	System	29 Jan 2021 17:50:48

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	30 Jan 2021 00:10:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:10:33
Data point term sent to Coder	System	29 Jan 2021 17:51:54
User entered 'Lidocaine'	Riley King (b) (4)	29 Jan 2021 17:51:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 17:51:41

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '5'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mL (mL)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:51:41
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User entered empty.	System	29 Jan 2021 17:51:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User entered empty.	System	29 Jan 2021 17:51:41

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (64)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:36
User entered empty.	System	29 Jan 2021 17:51:41



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: FOLIC ACID;MINERALS NOS;VITAMINS NOS, PRODUCTSYNONYM: THERA-M - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 15:38:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 15:38:46
Data point term sent to Coder	System	29 Jan 2021 17:52:55
User entered 'Thera-M'	Riley King (b) (4)	29 Jan 2021 17:52:42

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Nutritional deficiency'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'I'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'tablet (TABLET)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:52:42
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User entered '1'	System	29 Jan 2021 17:52:42



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User entered '1'	System	29 Jan 2021 17:52:42

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (65)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:41
User entered '804 (804)'	System	29 Jan 2021 17:52:42

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: SACCHARATED IRON OXIDE, PRODUCTSYNONYM: VENOFER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:42:30
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:42:30
Data point term sent to Coder	System	29 Jan 2021 17:53:58
User entered 'Venofer'	Riley King (b) (4)	29 Jan 2021 17:53:53

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:47
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:50
User entered 'Anemia'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:52
User entered '200'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:54
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:57
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:59
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:02
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:03
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:08
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:37
User entered '27 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:06
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:24:41
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:10
User entered '27 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:25:12
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:53:53
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User entered empty.	System	29 Jan 2021 17:53:53

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User entered empty.	System	29 Jan 2021 17:53:53

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (66)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:06:49
User entered empty.	System	29 Jan 2021 17:53:53

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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)	01 Feb 2021 15:42:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	01 Feb 2021 15:42:29
Data point term sent to Coder	System	29 Jan 2021 17:54:59
User entered 'Vancomycin'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1250'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:54:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User entered '1'	System	29 Jan 2021 17:54:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User entered '1'	System	29 Jan 2021 17:54:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (67)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:00
User entered '804 (804)'	System	29 Jan 2021 17:54:46

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:57:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 17:57:21
Data point term sent to Coder	System	29 Jan 2021 17:57:01
User entered 'Zosyn'	Riley King (b) (4)	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:01



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '3.375'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'g (g)'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:01
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User entered empty.	System	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User entered empty.	System	29 Jan 2021 17:56:01

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (68)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:06
User entered empty.	System	29 Jan 2021 17:56:01



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. 50/8.6 MG) from the medication name field as this is already recorded in the Dose and Unit field. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 09:22:33
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, PRODUCTSYNONYM: SENOKOT S - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 19:09:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 19:09:11
Data point term sent to Coder	System	31 Mar 2021 19:08:13
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. 50/8.6 MG) from the medication name field as this is already recorded in the Dose and Unit field. Update eCRF as appropriate.' answered with 'updated ' (Site from DM).	marissa Mueller (b) (4) (b) (4)	31 Mar 2021 19:07:22
DataPoint Un-verified.	marissa Mueller (b) (4)	31 Mar 2021 19:07:16
Coding entries removed.	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:07:16
User entered 'SENOKOT S' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:07:16
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. 50/8.6 MG) from the medication name field as this is already recorded in the Dose and Unit field. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:41:51

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
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, PRODUCTSYNONYM: SENOKOT S - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Mar 2021 09:37:33
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 09:37:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
Data point term sent to Coder	System	11 Mar 2021 19:50:20
Coding entries removed.	Riley King (b) (4)	11 Mar 2021 19:50:18
	(b) (4)	
User entered 'SENOKOT S 50/8.6 mg' reason for change: Data Entry Error	Riley King (b) (4)	11 Mar 2021 19:50:18
	(b) (4)	
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, PRODUCTSYNONYM: SENOKOT S - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Jan 2021 17:57:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Jan 2021 17:57:21
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 17:57:01
User entered 'Senokot S'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Constipation'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User closed query 'Per CDM CLR(Requery) : Thanks for the response. The dosage and unit needs to be updated in the respective fields. Kindly update the dose and dose unit field appropriately. Thanks.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:19:28
Query 'Per CDM CLR(Requery) : Thanks for the response. The dosage and unit needs to be updated in the respective fields. Kindly update the dose and dose unit field appropriately. Thanks.' answered with 'Updated ' (Site from DM).	Riley King (b) (4)	16 Mar 2021 15:38:59
DataPoint Un-verified.	Riley King (b) (4)	16 Mar 2021 15:38:51
User entered '50/8.6' reason for change: Per Query Resolution	Riley King (b) (4)	16 Mar 2021 15:38:51
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User opened query 'Per CDM CLR(Requery) : Thanks for the response. The dosage and unit needs to be updated in the respective fields. Kindly update the dose and dose unit field appropriately. Thanks.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:14:20
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 06:14:20
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate. ' answered with 'added actual doses to medication name ' (Site from DM).	Riley King (b) (4)	11 Mar 2021 19:50:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets. Please verify the dose and unit, and update as appropriate.  ' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4)	09 Mar 2021 07:41:48
	Riley King (b) (4) (b) (4)	29 Jan 2021 17:56:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Un-verified.	(b) (4) Riley King (b) (4)	16 Mar 2021 15:38:51
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4) Riley King (b) (4)	16 Mar 2021 15:38:51
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'tablet (TABLET)'	Riley King (b) (4) (b) (4)	29 Jan 2021 17:56:47

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'Per DM requery: Per previous response "Started 10/26/2020 ended10/26/2020" , kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 17:39:46
Query 'Per DM requery: Per previous response "Started 10/26/2020 ended10/26/2020" , kindly review and amend as appropriate.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	26 Feb 2021 16:05:56
User opened query 'Per DM requery: Per previous response "Started 10/26/2020 ended10/26/2020" , kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:02:57
User closed query 'Per CDM: Response noted , however kindly review the end date (26/01/2021) and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 10:02:57
Query 'Per CDM: Response noted , however kindly review the end date (26/01/2021) and amend as appropriate else clarify.' answered with 'Correct as entered. ' (Site from DM).	Riley King (b) (4)	04 Feb 2021 22:37:20
User opened query 'Per CDM: Response noted , however kindly review the end date (26/01/2021) and amend as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:48:32
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), (b) (6)	01 Feb 2021 07:47:02
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'Started 10/26/2020 ended10/26/2020. ' (Site from System).	Riley King (b) (4)	29 Jan 2021 22:40:27
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	29 Jan 2021 17:56:47
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:56:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	26 Feb 2021 16:05:47
User entered '26 Jan 2021'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:56:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User entered empty.	System	29 Jan 2021 17:56:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User entered empty.	System	29 Jan 2021 17:56:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (69)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:12
User entered empty.	System	29 Jan 2021 17:56:47

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: SACCHARATED IRON OXIDE, PRODUCTSYNONYM: VENOFER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:57:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 15:57:28
Data point term sent to Coder	System	29 Jan 2021 17:59:04
User entered 'Venofer'	Riley King (b) (4)	29 Jan 2021 17:58:23

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Anemia'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '200'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:58:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User entered empty.	System	29 Jan 2021 17:58:23

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User entered empty.	System	29 Jan 2021 17:58:23

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (70)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:17
User entered empty.	System	29 Jan 2021 17:58:23

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:15:26
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	30 Jan 2021 00:15:26
Data point term sent to Coder	System	29 Jan 2021 18:00:05
User entered 'Midazolam'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '2'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 17:59:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User entered empty.	System	29 Jan 2021 17:59:35

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User entered empty.	System	29 Jan 2021 17:59:35

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (71)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:32
User entered empty.	System	29 Jan 2021 17:59:35



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:58:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	03 Feb 2021 14:58:44
Data point term sent to Coder	System	29 Jan 2021 18:01:05
User entered 'Percocet'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '10/325'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:00:26
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User entered empty.	System	29 Jan 2021 18:00:26



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User entered empty.	System	29 Jan 2021 18:00:26

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (72)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:37
User entered empty.	System	29 Jan 2021 18:00:26

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:58:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:58:45
Data point term sent to Coder	System	29 Jan 2021 18:02:06
User entered 'Percocet'	Riley King (b) (4)	29 Jan 2021 18:01:12

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '5/325'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:12
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User entered empty.	System	29 Jan 2021 18:01:12

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User entered empty.	System	29 Jan 2021 18:01:12

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (73)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:40
User entered empty.	System	29 Jan 2021 18:01:12

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
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 SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 15:27:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 15:27:29
Data point term sent to Coder	System	29 Jan 2021 18:02:08
User entered 'Protonix'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Gastrointestinal bleed'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '40'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'twice daily (BID)'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:33:09
User closed query 'please verify as 11/21/20 per CM log' (Site from CRA).		18 Mar 2021 00:33:05
Query 'please verify as 11/21/20 per CM log' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 15:41:26
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 15:41:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 14:40:09
DataPoint Verified.		16 Mar 2021 14:39:45
User opened query 'please verify as 11/21/20 per CM log' (Site from CRA).		16 Mar 2021 14:34:39
User entered '21 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:01:58
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:01:58

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User entered '2'	System	29 Jan 2021 18:01:58

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User entered '1'	System	29 Jan 2021 18:01:58

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (74)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:44
User entered '804 (804)'	System	29 Jan 2021 18:01:58

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:34:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 21:34:23
Data point term sent to Coder	System	29 Jan 2021 18:03:09
User entered 'Ascorbic acid'	Riley King (b) (4)	29 Jan 2021 18:02:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '1000'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:19:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:19:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:19:32
	(b) (4)	
User entered '12 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:19:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:02:49
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User entered '1'	System	29 Jan 2021 18:02:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User entered '1'	System	29 Jan 2021 18:02:49

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (75)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:48
User entered '804 (804)'	System	29 Jan 2021 18:02:49



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 18:04:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 18:04:21
Data point term sent to Coder	System	29 Jan 2021 18:04:12
User entered 'Aspirin'	Riley King (b) (4)	29 Jan 2021 18:03:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Cardiac prophylaxis'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '81'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Oral (ORAL)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:04:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:20:01
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:20:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	24 Mar 2021 14:20:01
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	24 Mar 2021 14:20:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:03:25
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User entered '1'	System	29 Jan 2021 18:03:25



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User entered '1'	System	29 Jan 2021 18:03:25

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (76)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:51
User entered '804 (804)'	System	29 Jan 2021 18:03:25

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'please verify as 2.5mg-0.5mg as per source' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 14:29:46
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, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 22:13:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	(b) (4)	12 Mar 2021 22:13:49
Data point term sent to Coder	System	11 Mar 2021 19:54:24
Query 'please verify as 2.5mg-0.5mg as per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 19:54:04
Coding entries removed.	(b) (4)	
	Riley King (b) (4)	11 Mar 2021 19:53:57
User entered 'ALBUTEROL-IPRATROPIUM 2.5-0.5 MG/ 3ML' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	11 Mar 2021 19:53:57
User opened query 'please verify as 2.5mg-0.5mg as per source' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 17:40:48
DataPoint Un-verified.		03 Mar 2021 17:39:14
DataPoint Verified.		03 Mar 2021 17:37:29

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:04:29

[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/ALBUTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:06:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:06:23
Data point term sent to Coder	System	29 Jan 2021 18:05:14
User entered 'Albuterol-ipratropium 2.5 mg/ 3mL'	Riley King (b) (4) (b) (4)	29 Jan 2021 18:04:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:37:32
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:37:33
User entered 'Chronic obstructive pulmonary disease'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:32:07
User closed query 'please verify as 2.5-.5 mg as the amount of medication (mL is the dilution amount-see monitor' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:32:02
Query 'please verify as 2.5-.5 mg as the amount of medication (mL is the dilution amount-see monitor' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 15:42:27
User entered '2.5/0.5' reason for change: Per Query Resolution	Riley King (b) (4)	16 Mar 2021 15:42:19
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 14:40:26
DataPoint Verified.		16 Mar 2021 14:39:45
User opened query 'please verify as 2.5-.5 mg as the amount of medication (mL is the dilution amount-see monitor' (Site from CRA).		16 Mar 2021 14:32:28
Query 'please verify as mg; mL is the dilution not the amount of medication-see monitor' canceled (Site from CRA).		16 Mar 2021 14:31:48
User opened query 'please verify as mg; mL is the dilution not the amount of medication-see monitor' (Site from CRA).		16 Mar 2021 14:31:25
User closed query ' please verify as 2.5mg-0.5mg as per source' (Site from CRA).		16 Mar 2021 14:31:25
Query ' please verify as 2.5mg-0.5mg as per source' answered with 'per hospital record medication is recorded as 2.5-0.5mg/3 mL' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 19:54:36
User opened query ' please verify as 2.5mg-0.5mg as per source' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 17:41:28
User entered '3'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:04:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'please verify as mg; mL is the dilution not the amount of medication-see monitor' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:32:15
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:32:10
Query 'please verify as mg; mL is the dilution not the amount of medication-see monitor' answered with 'reconciled' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 15:42:35
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 14:40:29
DataPoint Verified.		16 Mar 2021 14:39:45
User opened query 'please verify as mg; mL is the dilution not the amount of medication-see monitor' (Site from CRA).		16 Mar 2021 14:31:43
User closed query 'please verify as mg as per hosp record' (Site from CRA).		16 Mar 2021 14:31:43
Query 'please verify as mg as per hosp record' answered with 'per hospital record medication is recorded as 2.5-0.5mg/3 mL' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 19:54:44
User opened query 'please verify as mg as per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 17:39:08
User closed query 'please verify 2.5 mg per source (mL is dilution amt)' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 11:06:37
Query 'please verify 2.5 mg per source (mL is dilution amt)' answered with 'in source dose is 3mL' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:39:00
User opened query 'please verify 2.5 mg per source (mL is dilution amt)' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:12:09
User entered 'mL (mL)'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:39
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:36
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:40
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:04:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:51
User closed query 'please verify as 21Oct per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 17:41:49
Query 'please verify as 21Oct per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	04 Feb 2021 22:40:02
User entered '21 Oct 2020' reason for change: Per Query Resolution	(b) (4)	04 Feb 2021 22:39:55
User opened query 'please verify as 21Oct per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:13:20
User entered '23 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:55
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:41:58
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:42:00
User entered '26 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:42:03
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:04:47
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User entered empty.	System	29 Jan 2021 18:04:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User entered empty.	System	29 Jan 2021 18:04:47

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (77)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:55
User entered empty.	System	29 Jan 2021 18:04:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:39:45
User closed query 'please change to lactated ringers for coding' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 14:28:50
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)	11 Mar 2021 19:56:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:56:52
Data point term sent to Coder	System	11 Mar 2021 19:56:27
Query 'please change to lactated ringers for coding' answered with 'reconciled' (Site from CRA).	Riley King (b) (4) (b) (4)	11 Mar 2021 19:55:37
Coding entries removed.	Riley King (b) (4) (b) (4)	11 Mar 2021 19:55:27
User entered 'Lactated ringers' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	11 Mar 2021 19:55:27
User opened query 'please change to lactated ringers for coding' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 19:04:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: LOSARTAN POTASSIUM;RAMIPRIL, PRODUCTSYNONYM: LR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:24:22

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Jan 2021 18:24:22
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	29 Jan 2021 18:23:31
User entered 'LR'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative infection, left hip'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '600'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:23:27
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User entered empty.	System	29 Jan 2021 18:23:27

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User entered empty.	System	29 Jan 2021 18:23:27

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (78)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:07:59
User entered empty.	System	29 Jan 2021 18:23:27



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
Query 'please verify as 1% per hosp record' canceled (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:40:48
User opened query 'please verify as 1% per hosp record' (Site from CRA).		16 Mar 2021 14:39:45
DataPoint Un-verified.		16 Mar 2021 14:28:43
DataPoint Verified.		16 Mar 2021 14:28:20
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)	02 Feb 2021 09:47:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 09:47:47
User entered 'Lidocaine 5%'	Riley King (b) (4)	29 Jan 2021 18:24:31
	(b) (4)	29 Jan 2021 18:24:23

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Post operative pain, generalized'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:04:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'I'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Other (OTHER)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'application'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Topical (TOPICAL)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:04:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query 'please verify as 28Oct2020 per CM log' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:33:38
DataPoint Verified.		18 Mar 2021 00:33:32
Query 'please verify as 28Oct2020 per CM log' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 15:44:35
	(b) (4)	
User entered '28 Oct 2020' reason for change: Data Entry Error	Riley King (b) (4)	16 Mar 2021 15:44:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 14:40:52
DataPoint Verified.		16 Mar 2021 14:39:45
User opened query 'please verify as 28Oct2020 per CM log' (Site from CRA).		16 Mar 2021 14:27:58
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:24:23
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User entered empty.	System	29 Jan 2021 18:24:23



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User entered empty.	System	29 Jan 2021 18:24:23

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (79)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:02
User entered empty.	System	29 Jan 2021 18:24:23

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:04:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
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)	18 Mar 2021 10:11:41
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:25:49
Data point term sent to Coder	System	11 Mar 2021 19:59:33
Coding entries removed.	Riley King (b) (4)	11 Mar 2021 19:59:31
User entered 'NICOTINE patch' reason for change: Data Entry Error	Riley King (b) (4)	11 Mar 2021 19:59:31
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)	02 Feb 2021 14:23:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:23:36
Data point term sent to Coder	System	29 Jan 2021 18:25:32
User entered 'Nicotine'	Riley King (b) (4)	29 Jan 2021 18:25:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Withdrawal prophylaxis'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '21'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mg (mg)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once daily (QD)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Topical (TOPICAL)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '22 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '28 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:25:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User entered '1'	System	29 Jan 2021 18:25:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User entered '1'	System	29 Jan 2021 18:25:09

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (80)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:05
User entered '804 (804)'	System	29 Jan 2021 18:25:09

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:20:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 18:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 18:28:23
Data point term sent to Coder	System	29 Jan 2021 18:27:34
User entered 'Pneumococcal vaccine'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Pneumonia prophylaxis'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0.5'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mL (mL)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'once (ONCE)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '14 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '14 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:26:37
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User entered empty.	System	29 Jan 2021 18:26:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User entered empty.	System	29 Jan 2021 18:26:37

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (82)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:30
User entered empty.	System	29 Jan 2021 18:26:37

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
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: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:54
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:20:04
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)	02 Feb 2021 00:15:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 00:15:33
Data point term sent to Coder	System	29 Jan 2021 18:28:34
User entered 'Normal saline'	Riley King (b) (4) (b) (4)	29 Jan 2021 18:27:35

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Hypotension'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '100'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Other (OTHER)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 15:04:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mL/hour'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 15:04:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'other (OTHER)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Continuous'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '24 Oct 2020'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 18:27:35
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User entered empty.	System	29 Jan 2021 18:27:35

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User entered empty.	System	29 Jan 2021 18:27:35

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (83)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:32
User entered empty.	System	29 Jan 2021 18:27:35



US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 15:04:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: SODIUM PHOSPHATE MONOBASIC (ANHYDROUS), PRODUCTSYNONYM: SODIUM BIPHOSPHATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 09:24:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 09:24:21
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:19:48
Data point term sent to Coder	System	11 Mar 2021 20:03:48
User entered 'sodium bisphosphate enema'	Riley King (b) (4) (b) (4)	11 Mar 2021 20:03:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'constipation'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '133'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'mL (mL)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'as needed (PRN)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

US3062151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 15:04:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'Rectal (RECTAL)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 15:04:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered empty.	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:19:40
User entered '25 Oct 2020'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered '0'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:19:42
User entered '28 Oct 2020'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:39:45
User entered 'No (N)'	Riley King (b) (4)	11 Mar 2021 20:03:46
	(b) (4)	

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User entered empty.	System	11 Mar 2021 20:03:46



**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User entered empty.	System	11 Mar 2021 20:03:46

**US3062151**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (84)**

**Generated On: 09 Jun 2021 15:04:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:08:35
User entered empty.	System	11 Mar 2021 20:03:46

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:04:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User closed query ' please add picc line insertion 26Oct20 per hos record' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:54:48
Query ' please add picc line insertion 26Oct20 per hos record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	11 Mar 2021 20:07:59
	(b) (4)	
User opened query ' please add picc line insertion 26Oct20 per hos record' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 19:09:57
Query 'please add picc line inseretion 26-28Oct20 per hos record' canceled (Site from CRA).		03 Mar 2021 19:09:26
User opened query 'please add picc line inseretion 26-28Oct20 per hos record' (Site from CRA).		03 Mar 2021 17:56:33
User closed query 'please add insertion of picc line 10/27/2020 per hosp record' (Site from CRA).		03 Mar 2021 17:56:33
Query 'please add insertion of picc line 10/27/2020 per hosp record' answered with 'correct as entered as per inserting IV' (Site from CRA).	Colton King (b) (4)	04 Feb 2021 21:33:31
	(b) (4)	
User opened query 'please add insertion of picc line 10/27/2020 per hosp record' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:14:38
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:37:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	20 Oct 2020 21:21:09
User entered 'No (N)'	marissa Mueller (b) (4)	02 Sep 2020 14:15:45
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:30:51
User entered '14 Oct 2020'	Jeri King (b) (4)	20 Oct 2020 21:21:26

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:30:51
User entered 'Left Hip Replacement'	Jeri King (b) (4)	20 Oct 2020 21:21:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:30:51
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	20 Oct 2020 21:21:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:30:51
User entered empty.	Jeri King (b) (4)	20 Oct 2020 21:21:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:22:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:01
DataPoint Un-verified.		08 Nov 2020 14:33:00
DataPoint Verified.		08 Nov 2020 14:30:51
User entered '24 Oct 2020'	marissa Mueller (b) (4)	29 Oct 2020 21:07:43
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:22:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:04
DataPoint Un-verified.		08 Nov 2020 14:32:53
DataPoint Verified.		08 Nov 2020 14:30:51
User entered 'revision left hip replacement'	marissa Mueller (b) (4)	29 Oct 2020 21:07:43
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:22:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Nov 2020 14:32:56
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:30:51
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	29 Oct 2020 21:07:43
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:22:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:08
DataPoint Un-verified.		08 Nov 2020 14:32:58
DataPoint Verified.		08 Nov 2020 14:30:51
User entered empty.	marissa Mueller (b) (4)	29 Oct 2020 21:07:43
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:05:11
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 22:03:43
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:05:09
User entered 'Irrigation and debridement of left hip'	Riley King (b) (4)	29 Jan 2021 22:03:43
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:05:06
User entered 'Adverse Event (AE)'	Riley King (b) (4)	29 Jan 2021 22:03:43
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:26
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:05:04
User entered empty.	Riley King (b) (4)	29 Jan 2021 22:03:43
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:30
User entered '25 Oct 2020'	Riley King (b) (4)	29 Jan 2021 22:04:16
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:32
User entered 'Exchange of the poly and femoral head of the implants'	Riley King (b) (4)	29 Jan 2021 22:04:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:35
User entered 'Adverse Event (AE)'	Riley King (b) (4)	29 Jan 2021 22:04:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 17:57:46
User entered empty.	Riley King (b) (4)	29 Jan 2021 22:04:16
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:34:55
User entered '23 Oct 2020'	Riley King (b) (4)	02 Mar 2021 14:19:44
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:34:58
User entered 'electrocardiogram'	Riley King (b) (4)	02 Mar 2021 14:19:44
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:04:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:35:06
User entered 'Adverse Event (AE)'	Riley King (b) (4)	02 Mar 2021 14:19:44
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:35:04
User entered empty.	Riley King (b) (4)	02 Mar 2021 14:19:44
	(b) (4)	

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 15:04:29**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:40:54
User entered '22 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:55:52
	(b) (4)	



US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:40:56
User entered 'Esophagogastroduodenoscopy'	Janna Martinez (b) (4)	02 Mar 2021 20:55:52
	(b) (4)	

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:40:58
User entered 'Adverse Event (AE)'	Janna Martinez (b) (4)	02 Mar 2021 20:55:52
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:41:00
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:55:52
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:44
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '21 Oct 2020'	Janna Martinez (b) (4)	02 Mar 2021 20:59:09
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:04:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:44
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'computerized tomography scan, abdominal'	Janna Martinez (b) (4)	02 Mar 2021 20:59:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:44
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'Adverse Event (AE)'	(b) (4) Janna Martinez (b) (4)	02 Mar 2021 20:59:09
	(b) (4)	

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 15:04:29**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:44
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	02 Mar 2021 20:59:09
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:04:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '26 Oct 2020'	Riley King (b) (4)	11 Mar 2021 20:07:50
	(b) (4)	



**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
User entered 'PICC line insertion'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 20:07:50

**US3062151**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:04:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered 'Adverse Event (AE)'	Riley King (b) (4)	11 Mar 2021 20:07:50
	(b) (4)	

US3062151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:04:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:23:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:10:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered empty.	Riley King (b) (4)	11 Mar 2021 20:07:50
	(b) (4)	

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
User entered '21/Oct/2020 18:27'	System	21 Oct 2020 18:27:37

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:04:29

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
User entered '30/Oct/2020 14:02'	System	30 Oct 2020 14:02:18

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:04:29

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:26:19
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 14:02:18

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
User entered '30/Oct/2020 14:26'	System	30 Oct 2020 14:26:30



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:04:29

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:50:02
DataPoint Verified.		04 Nov 2020 18:41:27
User entered 'I'		30 Oct 2020 14:26:30

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.		21 Oct 2020 18:27:29
User entered 'USA-US090-2020-MRNA-1273-P301000005'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '30/Nov/2020 16:50'	System	30 Nov 2020 16:50:19

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:04:29

**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)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:32:16
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 16:50:19

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '01/Feb/2021 12:32'	System	01 Feb 2021 17:32:31

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:04:29

**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)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:55:59
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 17:32:31

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '05/Feb/2021 13:56'	System	05 Feb 2021 13:56:11

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:04:29

**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)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 17:02:09
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 13:56:11

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '01/Mar/2021 17:02'	System	01 Mar 2021 17:02:24



US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:04:29

**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)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 21:08:45
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 17:02:24

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered	System	21 Oct 2020 18:26:57
'USA-US090-2020-MRNA-1273-P301000005'		

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Yes (Y)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'No (N)'	System	21 Oct 2020 18:26:57

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Richard'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Glover'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '700 Medical Center Dr.'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'Newton'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered 'KS'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:27:29
User entered '67114'	System	21 Oct 2020 18:26:57

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:41:27
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:02:03
User entered 'US'	System	21 Oct 2020 18:27:37



**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	02 Mar 2021 21:07:29
User entered '7'	System	01 Mar 2021 17:02:24
User entered '6'	System	05 Feb 2021 13:56:11
User entered '5'	System	01 Feb 2021 17:32:31
User entered '4'	System	30 Nov 2020 16:50:19
User entered '3'	System	30 Oct 2020 14:26:30
User entered '2'	System	30 Oct 2020 14:02:18
User entered '1'	System	21 Oct 2020 18:27:37

**US3062151**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 15:04:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
User entered '02/Mar/2021 16:07'	System	02 Mar 2021 21:07:29

US3062151

Folder: SAE USA-US090-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:04:29

**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)	05 Apr 2021 19:25:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:38:41
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 21:08:45
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 21:07:29