

US3062075 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:57:41

All time stamps listed in this document are displayed in GMT

US3062075

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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Participant ID

US3062075

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

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US3062075

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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

Visit date (dd MMM yyyy)	04 AUG 2020
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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	SCRN
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US3062075

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
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 15:22:07

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	04 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

US3062075

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	CARDIAC PALPITAION
Start date (dd MMM yyyy)	01 JAN 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 (2)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	01 JAN 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 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	01 JAN 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)	_____

US3062075

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	01 JAN 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	FIBROID TUMOR
Start date (dd MMM yyyy)	01 JAN 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	01 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
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 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	DEPRESSION
Start date (dd MMM yyyy)	01 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 (8)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	HYPERTENSION
Start date (dd MMM yyyy)	15 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	PULMONARY HYPERTENSION
Start date (dd MMM yyyy)	13 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	CONSTIPATION, RECURRENT
Start date (dd MMM yyyy)	18 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	15 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	REBOUND ABDOMINAL TENDERNESS
Start date (dd MMM yyyy)	22 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	INSOMNIA
Start date (dd MMM yyyy)	13 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	01 NOV 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)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	DORSALGIA
Start date (dd MMM yyyy)	13 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	GENERAL MUSCLE CRAMPING
Start date (dd MMM yyyy)	13 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Condition	GENERAL MUSCLE SPASM
Start date (dd MMM yyyy)	13 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3062075

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 AUG 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:14
Height (xxx.x)	157.0 cm
Weight (xxx.x)	76.6 lb
BMI (xxx.x)	14.12560 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 15:22:07

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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 15:22:00

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*) 4 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*) 01 JAN 1982

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:07

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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)	True
<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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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

Visit date (dd MMM yyyy)	04 AUG 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184664

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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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)	4 AUG 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 14:14
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	16:29 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 16:29
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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 15:22:07

Generated On: 09 Jun 2021 14:57:41

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 15:58 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 15:58

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 15:22:07

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	15:13 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:00	04 AUG 2020 15:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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 14:57:41

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 16:39

PC Open Date & Time

04 AUG 2020 16:18

PC Close Date & Time

04 AUG 2020 18:48

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**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 98.4 °F

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

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

PC Time Stamp	04 AUG 2020 19:52
PC Open Date & Time	04 AUG 2020 19:43
PC Close Date & Time	05 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**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

05 AUG 2020 18:22

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 21:31

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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

07 AUG 2020 20:51

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

08 AUG 2020 21:37

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 18:54

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 16:54

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 16:41

PC Open Date & Time

04 AUG 2020 16:18

PC Close Date & Time

04 AUG 2020 18:48

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 19:53

PC Open Date & Time

04 AUG 2020 19:43

PC Close Date & Time

05 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 18:23

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 21:32

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 20:50

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 21:38

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 18:55

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**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 AUG 2020 16:54

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**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 ☐

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:42
PC Open Date & Time	04 AUG 2020 16:18
PC Close Date & Time	04 AUG 2020 18:48

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**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 ☐

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:47
PC Open Date & Time	04 AUG 2020 19:43
PC Close Date & Time	05 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:24
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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)

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 21:33
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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 ☒

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:52
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:39
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

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EAB) (1725)



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:57
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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 ☒

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 16:55
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3062075

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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)	1 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:42
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	109 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:18
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3062075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 12:47

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

US3062075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	1 SEP 2020 11:55

US3062075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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



US3062075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**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

98.0 °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

01 SEP 2020 13:26

PC Open Date & Time

01 SEP 2020 13:07

PC Close Date & Time

01 SEP 2020 15:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	02 SEP 2020 08:11
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**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

97.2 °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

02 SEP 2020 20:52

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 22:47

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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

97.2 °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 22:06

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**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):

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

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

PC Time Stamp 05 SEP 2020 20:52

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:25

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 10:46

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**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

01 SEP 2020 13:29

PC Open Date & Time

01 SEP 2020 13:07

PC Close Date & Time

01 SEP 2020 15:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**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

02 SEP 2020 08:23

PC Open Date & Time

01 SEP 2020 16:32

PC Close Date & Time

02 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**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

02 SEP 2020 20:53

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**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

03 SEP 2020 22:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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

04 SEP 2020 22:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**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

05 SEP 2020 20:53

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**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

06 SEP 2020 22:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**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

08 SEP 2020 10:47

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**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 ☐

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:32
PC Open Date & Time	01 SEP 2020 13:07
PC Close Date & Time	01 SEP 2020 15:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**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 ☐

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 08:25
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:54
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 22:49
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:08
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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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US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:27
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**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 ☒



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 10:49
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:00

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT3



US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 11:38
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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.*

US3062075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

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

Collection date (dd MMM yyyy)	26 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:50 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 SEP 2020 11:50
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US3062075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:07

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 11:46:58

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

12 OCT 2020 17:36:23

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 18:38:22

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 00:02:35

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59



US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 21:16:33

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 12:37:22

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 10:49:47

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 00:02:23

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 12:18:01
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 20:03:51
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

17 DEC 2020 13:37:44

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

24 DEC 2020 17:35:37

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

02 JAN 2021 12:39:49

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 17:08:45

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

16 JAN 2021 10:13:47

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

21 JAN 2021 10:57:09

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

28 JAN 2021 17:59:56

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

04 FEB 2021 00:02:48

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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	11 FEB 2021 22:32:46
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 08:00:49
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

25 FEB 2021 15:40:46

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

04 MAR 2021 00:04:31

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

11 MAR 2021 00:33:23

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

18 MAR 2021 01:31:57

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

25 MAR 2021 20:23:36

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

02 APR 2021 11:48:33

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

08 APR 2021 00:03:21

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

15 APR 2021 07:22:46

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

22 APR 2021 00:03:02

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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

29 APR 2021 00:03:05

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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 <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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 628

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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 <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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 726

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 761

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59



US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2022 23:59

US3062075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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



US3062075

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:57:41

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		04 MAR 2021 00:03:26

US3062075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3062075

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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

---

Visit date (dd MMM yyyy)	24 FEB 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"/>

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Folder OID	VISIT4
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US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 13:59
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:51:35

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3062075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

14:43 (24 HR)

Collection date and time (derived)

24 FEB 2021 14:43

US3062075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062075

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

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*

**US3062075**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062075

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:41

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"/>

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3062075

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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

Visit date (dd MMM yyyy)	26 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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US3062075

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3062075

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Height	157.0 cm
Weight	76.1 kg
BMI (xxx.x)	30.87346

US3062075

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Height	157.0 cm
Weight	76.1 kg
BMI (xxx.x)	30.87346
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 14:51
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG



US3062075

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Height	157.0 cm
Weight	76.1 kg
BMI (xxx.x)	30.87346
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	17:03 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 17:03
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3062075

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3062075

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 16:31 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 16:31

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

What was the frequency of the study treatment dosing? ONCE

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

US3062075

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00-23:59)	15:03 (24 HR)
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Collection date and time (derived)	26 JAN 2021 15:03
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US3062075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 26 JAN 2021

Collection time (00:00 - 23:59) 14:59

Collection Date and Time (derived) 26 JAN 2021 14:59

US3062075

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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



US3062075

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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)	24 FEB 2021
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 13:59
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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)	24 FEB 2021
Time of assessment (00:00-23:59)	15:34 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:34
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062075

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3062075

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 15:02 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 15:02

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

US3062075

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3062075

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062075

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

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

Visit date (dd MMM yyyy)	25 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	OLD57
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US3062075

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:14 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 14:14
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	81 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062075

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 14:25 (24 HR)

Collection date and time (derived) 25 MAR 2021 14:25

US3062075

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:55:17

Generated On: 09 Jun 2021 14:57:41

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	USA-US090-2021-MRNA-1273-P30 1000001
Adverse event	FRACTURE OF SUPERIOR RIM RIGHT PUBIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	8 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

---

SUBJECT OUT OF TOWN  
ON 12/27/2020. SUBJECT  
ACCIDENTALLY FELL AND  
WENT TO THE HOSPITAL  
WHERE SHE WAS DIAGNOSED  
WITH FRACTURE OF THE  
PELVIS. SUBJECT IN FOR OL  
SUBJECT DECISION VISIT.  
PATIENT REPORTS DISCHARGE  
FROM HOSPITAL TOOK PLACE  
ON 08JAN2021 AND SUBJECT  
WAS TRANSPORTED TO A  
REHAB FACILITY ON  
09JAN2021. SUBJECT UNSURE  
OF DATE RELEASED FROM  
REHAB. SUBJECT BEGAN OT  
AND PT TWICE WEEKLY UPON  
RETURNING HOME. PATIENT  
SIGNED RORS SITE WILL  
UPDATE SAE UPON RECEIPT OF  
NEW INFORMATION.  
RECEIVED MEDICAL RECORDS  
FROM PARIS REGIONAL  
MEDICAL CENTER WHERE  
SUBJECT WAS DIAGNOSED  
WITH SAE. WHILE IN THE  
HOSPITAL SUBJECT HAD  
MULTIPLE PROCEDURES DONE,  
CON PROCEDURE FORM  
UPDATED. SUBJECT ALSO GOT  
DIAGNOSED WITH MORE AES  
AE FORM UPDATED. ALSO  
RECEIVED MEDICATION LIST  
AND MAR CONMED FORM  
UPDATED. ALL NEW AES,



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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

---

PROCEDURES, AND  
MEDICATIONS ENTERED INTO  
EDC. 3/15/2021 SUBJECT  
CONTACTED SITE TO NOTIFY  
AND CHANGE IN SAE. SUBJECT  
HAS FINISHED PT AND OT.  
SUBJECT HAS ALSO STOPPED  
TAKING PRN PAIN  
MEDICATION FOR SAE. UPDATE  
RECORDED IN SOURCE AND  
EDC. SUBJECT'S SAE  
CONSIDERED RESOLVED AT  
THIS TIME.

---

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 (5)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	BILATERAL LOWER EXTREMITY EDEMA
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)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 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 (6)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 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 (7)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID

Adverse event

FRACTURE OF THE SACRUM

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 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (8)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	HYPOXIA
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)	2 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
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 (8)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (9)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID

Adverse event

GENERALIZED 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)

28 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (10)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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AEID

Adverse event

RIGHT INFERIOR PUBIS  
FRACTURE

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 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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)	

US3062075

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (12)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Form: Adverse Events (12)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (13)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (13)

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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 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) 09 Apr 2021 13:20:00

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AEID

Adverse event

GENERALIZED NAUSEA

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)

28 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 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 (14)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (15)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	MITRAL REGURGITATION
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)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (15)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (16)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	TRICUSPID REGURGITATION
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)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (16)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (17)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	CONCENTRIC LEFT VENTRICULAR HYPERTROPHY
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)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 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 (18)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	DILATED ATRIUM
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)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (18)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (19)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	CARDIOMEGALY WITHOUT ACUTE ABNORMALITY
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)	2 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 <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 (20)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	LOW LUNG VOLUME
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)	2 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (20)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (21)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID

Adverse event

ATHEROSCLEROTIC  
VASCULAR CALCIFICATION

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)

29 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 (21)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 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 (22)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 <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 (23)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	BIBASILAR DEPENDENT ATELECTASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 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 (24)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 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 (26)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 09 Apr 2021 13:20:00

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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 (28)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Adverse Events

Form: Adverse Events (28)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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 (29)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

AEID	
Adverse event	BIBASILAR ATELECTASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (29)

Data signed: (b) (4) 09 Apr 2021 13:20:00

Generated On: 09 Jun 2021 14:57:41

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)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:25:51

Generated On: 09 Jun 2021 14:57:41

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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 (1)

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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)		01 JAN 2005
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 20:25:46

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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 JAN 1990
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 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 (3)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication CARDIAC PALPITATION

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 (3)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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 JAN 2005
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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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Form: Prior/Concomitant Medication and Vaccination (5)

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Name of Medication PAROXITINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 (5)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 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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Form: Prior/Concomitant Medication and Vaccination (6)

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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 20:25:46

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	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)		13 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)		13 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 JAN 2021	
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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Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication MIRALAX

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION, RECURRENT

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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Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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



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Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING DEPRESSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication ZANTAC

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 75

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 (11)

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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)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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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Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	9 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication BISACODYL

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION, RECURRENT

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 (13)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication COLACE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION, RECURRENT

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication CYMBALTA

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 (15)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 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 (16)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication LIDODERM 5%

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication METAXALONE

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED MUSCLE  
CRAMPING

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	28 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 (19)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication CALCIUM CARBONATE  
VITAMIN D3 600 MG

Prophylaxis Yes ☐  
No ☒

Indication FRACTURE OF SUPERIOR RIM  
RIGHT PUBIS

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 (20)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED PAIN

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 (21)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)		29 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication NORCO 5/325

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 ☐  
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 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)		29 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication NORCO 10/325

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 ☐  
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 20:25:46

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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)		29 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 1 JAN 2021		
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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication ALBUTEROL/IPRATROPIUM

Prophylaxis Yes ☐  
No ☒

Indication ACUTE RESPIRATORY FAILURE

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication LEVALBUTEROL HCL

Prophylaxis Yes ☐  
No ☒

Indication ACUTE RESPIRATORY FAILURE

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	9 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication BACTERIOSTATIC WATER

Prophylaxis Yes ☐  
No ☒

Indication FRACTURE OF SUPERIOR RIM  
RIGHT PUBIS

Dose per administration 12

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 EVERY 6 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication BENZOCAINE/MENTHOL

Prophylaxis Yes ☐  
No ☒

Indication FRACTURE OR SUPERIOR RIM  
RIGHT PUBIS

Dose per administration 1

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

If dose unit is Other, specify LOZENGE

Frequency once daily ☐  
twice 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 (28)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication MORPHINE 4MG/ML

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED PAIN

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 (29)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication ZOFRAN 4MG/ML

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 (30)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication ZOFRAN 4MG/2ML

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 (31)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication DILAUDID(HYDROMORPHONE  
0.5MG/0.5ML)

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED PAIN

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication NORCO 5/325

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

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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)		29 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
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 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 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 (36)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication BISACODYL

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION, RECURRENT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	29 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 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 (37)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED PAIN

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 (37)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication LASIX(FUROSEMIDE)

Prophylaxis Yes ☐  
No ☒

Indication HYPOXIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	2 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication LASIX(FUROSEMIDE)

Prophylaxis Yes ☐  
No ☒

Indication HYPOXIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)		3 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication NORCO 7.5/325

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 9 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (42)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (43)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication FRACTURE OF SUPERIOR RIM  
RIGHT PUBIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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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)	5 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

Name of Medication BISOCODYL

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION, RECURRENT

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 (44)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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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 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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 02 Apr 2021 20:25:46

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Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication HYPOXIA

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 02 Apr 2021 20:25:46

Generated On: 09 Jun 2021 14:57:41

	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)	02 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:25:51

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 JAN 2021	ECHO WITH DOPPLER	Adverse Event	
2 JAN 2021	CHEST X-RAY	Adverse Event	
30 DEC 2020	CHEST CT	Adverse Event	
28 DEC 2020	CHEST X-RAY	Adverse Event	
29 DEC 2020	CHEST X-RAY WITH CONTRAST	Adverse Event	
29 DEC 2020	CHEST X-RAY WITHOUT CONTRAST	Adverse Event	
16 JAN 2021	PHYSICAL THERAPY	Adverse Event	
16 JAN 2021	OCCUPATIONAL THERAPY	Adverse Event	



US3062075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:41

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

US3062075

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:57:41

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 ☐

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	04/JAN/2021 13:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	28/JAN/2021 14:22
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	29/JAN/2021 16:10
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	04/FEB/2021 12:58
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	17/FEB/2021 10:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



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Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:28
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	25/FEB/2021 13:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	10/MAR/2021 12:15
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:44
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

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	18/MAR/2021 07:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 02 Apr 2021 20:25:52

Generated On: 09 Jun 2021 14:57:41

SAEID	USA-US090-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10
Date of submission (Pre-filled from custom function)	
<b>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.</b>	

Audit

US3062075 (Prod: Alliance for Multispecialty Research, LLC)

**US3062075**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:57:41**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
User entered 'US3062075'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:32



**US3062075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 21:04:51
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:33

US3062075

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Riley King (b) (4)	04 Aug 2020 21:04:51
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'SCRN'	System	04 Aug 2020 21:04:51

US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered (b) (6) 1942'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:34

US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '77'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'YEARS'	System	06 Aug 2020 00:14:26

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '77'	System	04 Aug 2020 21:05:10



US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 00:15:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 00:15:04
User entered 'Female (F)' reason for change: Data Entry Error	Janna Martinez (b) (4)	06 Aug 2020 00:15:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 00:14:26
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'I'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26

US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	



US3062075

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:14:26

**US3062075**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:57:41**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:14:26
	(b) (4)	

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '04 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 21:05:10

**US3062075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:57:41**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Aug 2020'	System	04 Aug 2020 21:05:10

**US3062075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:57:41**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2020'	System	04 Aug 2020 21:05:10

**US3062075**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:57:41**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Amendment 1 (1)'	Riley King (b) (4)	04 Aug 2020 21:05:10
	(b) (4)	

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 21:05:10
	(b) (4)	



US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 21:05:10

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 21:05:10

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:05:10
	(b) (4)	

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:33

US3062075

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'I'	System	04 Aug 2020 21:05:17

**US3062075**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 14:57:41**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 21:05:17
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:57:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 22:40:04
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Cardiac disorders, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitations - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	06 Aug 2020 07:30:09
Data point term sent to Coder	(b) (4)	
User entered 'CARDIAC PALPITAION'	System	05 Aug 2020 22:42:03
	Janna Martinez (b) (4)	05 Aug 2020 22:41:15
	(b) (4)	



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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jan 2005'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:41:15
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:41:15

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 22:41:15

US3062075

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 22:41:15

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:41:15
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2005'	System	05 Aug 2020 22:41:15

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2005'	System	05 Aug 2020 22:41:15

**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:41:15



**US3062075**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:41:15

US3062075

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 22:44:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 22:44:04
Data point term sent to Coder	System	05 Aug 2020 22:43:06
User entered 'HYPERLIPIDEMIA'	Janna Martinez (b) (4) (b) (4)	05 Aug 2020 22:42:18

US3062075

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '01 Jan 2005'	Janna Martinez (b) (4)	05 Aug 2020 22:42:18
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:42:18

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 22:42:18
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4)	05 Aug 2020 22:42:18
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:42:18
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2005'	System	05 Aug 2020 22:42:18



**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2005'	System	05 Aug 2020 22:42:18

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:42:18

**US3062075**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:42:18

US3062075

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 22:45:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 22:45:04
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 22:44:06
User entered 'HYPOTHYROIDISM'	Janna Martinez (b) (4)	05 Aug 2020 22:44:04
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jan 1990'	Janna Martinez (b) (4)	05 Aug 2020 22:44:04

US3062075

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4) (b) (4)	05 Aug 2020 22:44:04

**US3062075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 22:44:04

US3062075

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:44:04
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:44:04
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 1990'	System	05 Aug 2020 22:44:04

**US3062075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '1990'	System	05 Aug 2020 22:44:04

**US3062075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:44:04

**US3062075**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	05 Aug 2020 22:44:04

US3062075

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 15:50:39
	(b) (4)	
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:16:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'FIBROID TUMOR is the Associated condition and EDC has been updated ' (Site from DM).	Colton King (b) (4)	01 Sep 2020 15:16:56
	(b) (4)	
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:44:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 22:48:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 22:48:08
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 22:47:09
User entered 'COMPLETE HYSTERECTOMY'	Janna Martinez (b) (4)	05 Aug 2020 22:46:19
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jan 1982'	Janna Martinez (b) (4)	05 Aug 2020 22:46:19

US3062075

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:46:19
	(b) (4)	



US3062075

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:16:53
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Updated ' (Site from DM).	Colton King (b) (4) (b) (4)	01 Sep 2020 15:17:53
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	01 Sep 2020 15:17:19
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:44:27
User entered 'Yes (Y)'	Janna Martinez (b) (4) (b) (4)	05 Aug 2020 22:46:19

US3062075

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '01 Jan 1982' reason for change: Data Entry Error	Colton King (b) (4)	01 Sep 2020 15:17:19
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 22:46:19
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:46:19
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 1982'	System	05 Aug 2020 22:46:19

US3062075

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:41

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '1982'	System	05 Aug 2020 22:46:19

**US3062075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 1982'	System	01 Sep 2020 15:17:19
User entered empty.	System	05 Aug 2020 22:46:19

**US3062075**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '1982'	System	01 Sep 2020 15:17:19
User entered empty.	System	05 Aug 2020 22:46:19

US3062075

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 15:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 15:14:47
Data point term sent to Coder	System	01 Sep 2020 15:13:36
User entered 'Fibroid Tumor'	Colton King (b) (4) (b) (4)	01 Sep 2020 15:13:23



**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jan 1982'	(b) (4) Colton King (b) (4) (b) (4)	01 Sep 2020 15:13:23

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Colton King (b) (4)	01 Sep 2020 15:13:23
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	01 Sep 2020 15:13:23
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '01 Jan 1982'	Colton King (b) (4)	01 Sep 2020 15:13:23
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	01 Sep 2020 15:13:23

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 1982'	System	01 Sep 2020 15:13:23

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '1982'	System	01 Sep 2020 15:13:23

**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 1982'	System	01 Sep 2020 15:13:23



**US3062075**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '1982'	System	01 Sep 2020 15:13:23

US3062075

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 18:55:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 18:55:56
Data point term sent to Coder	System	28 Sep 2020 18:55:25
User entered 'Gastroesophageal Reflux Disease'	Jeri King (b) (4)	28 Sep 2020 18:55:09

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jul 2020'	(b) (4) Jeri King (b) (4)	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Jeri King (b) (4)	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Jeri King (b) (4)	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Jeri King (b) (4)	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Jeri King (b) (4)	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jul 2020'	System	28 Sep 2020 18:55:09



**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2020'	System	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Sep 2020 18:55:09

**US3062075**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Sep 2020 18:55:09

US3062075

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:01:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:01:39
Data point term sent to Coder	System	28 Sep 2020 19:00:38
User entered 'Depression'	Jeri King (b) (4)	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '01 Jan 2015'	(b) (4) Jeri King (b) (4)	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Jeri King (b) (4)	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Jeri King (b) (4)	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Jeri King (b) (4)	28 Sep 2020 19:00:16



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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Jeri King (b) (4)	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2015'	System	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2015'	System	28 Sep 2020 19:00:16

**US3062075**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Sep 2020 19:00:16

US3062075

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:41

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Sep 2020 19:00:16

US3062075

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 22:51:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 22:51:23
Data point term sent to Coder	System	28 Jan 2021 22:50:53
User entered 'Hypertension'	Riley King (b) (4) (b) (4)	28 Jan 2021 22:50:19

US3062075

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '15 Jan 2019'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:50:19

**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:50:19
	(b) (4)	



**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:50:19

US3062075

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:50:19

**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:50:19
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:50:19

**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:50:19

**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:50:19

**US3062075**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:50:19

US3062075

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary hypertension, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 22:51:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 22:51:22
Data point term sent to Coder	System	28 Jan 2021 22:50:55
User entered 'Pulmonary hypertension'	Riley King (b) (4)	28 Jan 2021 22:50:44



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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '13 Jan 2019'	Riley King (b) (4)	28 Jan 2021 22:50:44
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:50:44
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 22:50:44
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:50:44

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:50:44
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:50:44

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:50:44

**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:50:44



**US3062075**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:50:44

US3062075

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
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 chronic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jan 2021 20:50:27
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Jan 2021 20:50:27
Data point term sent to Coder	System	28 Jan 2021 22:51:57
User entered 'Constipation, recurrent'	Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:20

US3062075

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '18 Jan 2019'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:20

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:51:20
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 22:51:20
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:20

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:20

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:51:20



**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:51:20

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:51:20

**US3062075**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:51:20

US3062075

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 22:52:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 22:52:23
Data point term sent to Coder	System	28 Jan 2021 22:51:57
User entered 'Osteoporosis'	Riley King (b) (4)	28 Jan 2021 22:51:52

**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '15 Jan 2019'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:52

**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:51:52
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:52

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:52



**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:51:52

US3062075

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:57:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:51:52

**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:51:52

**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:51:52

**US3062075**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:51:52

US3062075

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal rebound tenderness, LLT: Abdominal rebound tenderness - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jan 2021 23:27:50
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	31 Jan 2021 23:27:50
Data point term sent to Coder	System	28 Jan 2021 22:52:58
User entered 'Rebound abdominal tenderness'	Riley King (b) (4)	28 Jan 2021 22:52:26

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '22 Jan 2019'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:26

**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:26



**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:26

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:26

**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Riley King (b) (4)	28 Jan 2021 22:52:26
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:57:41

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:52:26

**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:52:26

**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:52:26

**US3062075**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:52:26

US3062075

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 22:53:23
Data point term sent to Coder	(b) (4)	
User entered 'Insomnia'	System	28 Jan 2021 22:52:58
	Riley King (b) (4)	28 Jan 2021 22:52:47
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '13 Jan 2019'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 22:52:47
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	28 Jan 2021 22:52:47

**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:52:47



**US3062075**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	28 Jan 2021 22:52:47

US3062075

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
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: Chronic back pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 15:21:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 15:21:58
Data point term sent to Coder	System	16 Feb 2021 15:21:17
User entered 'Chronic back pain'	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 15:20:26

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Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '01 Nov 2018'	Cayla Lawless (b) (4)	16 Feb 2021 15:20:26

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 15:20:26
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 15:20:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered empty.	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 15:20:26
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	Cayla Lawless (b) (4)	16 Feb 2021 15:20:26

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Nov 2018'	System	16 Feb 2021 15:20:26



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**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2018'	System	16 Feb 2021 15:20:26

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 15:20:26

**US3062075**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 15:20:26

US3062075

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:57:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(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: Dorsalgia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 16:58:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 16:58:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 16:58:42
User entered 'Dorsalgia'	Cayla Lawless (b) (4)	16 Feb 2021 16:58:28
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered '13 Jan 2019'	Cayla Lawless (b) (4)	16 Feb 2021 16:58:28
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	(b) (4) Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:58:28

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:58:28
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered empty.	Cayla Lawless (b) (4)	16 Feb 2021 16:58:28
	(b) (4)	



**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	(b) (4) Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:58:28

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	16 Feb 2021 16:58:28

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	16 Feb 2021 16:58:28

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:58:28

**US3062075**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:58:28

US3062075

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
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: Muscle cramp - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:24:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:24:58
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 16:59:45
User entered 'General muscle cramping'	Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '13 Jan 2019'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:57:41

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered '0'	Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	



**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered empty.	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered '0'	Cayla Lawless (b) (4)	16 Feb 2021 16:58:48
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	16 Feb 2021 16:58:48

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	16 Feb 2021 16:58:48

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:58:48

**US3062075**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:58:48

US3062075

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:57:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
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: Muscle spasm - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:24:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:24:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 16:59:43
User entered 'General muscle spasm'	Cayla Lawless (b) (4)	16 Feb 2021 16:59:17
	(b) (4)	



US3062075

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:57:41

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '13 Jan 2019'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:59:17
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:59:17
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered 'Yes (Y)'	(b) (4) Cayla Lawless (b) (4)	16 Feb 2021 16:59:17
	(b) (4)	

US3062075

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:57:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered empty.	Cayla Lawless (b) (4)	16 Feb 2021 16:59:17

**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User entered '0'	Cayla Lawless (b) (4)	16 Feb 2021 16:59:17

US3062075

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:57:41

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'Jan 2019'	System	16 Feb 2021 16:59:17

**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '2019'	System	16 Feb 2021 16:59:17

**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:59:17



**US3062075**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered empty.	System	16 Feb 2021 16:59:17

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '04 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 22:51:15

**US3062075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '14:14'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered '04 Aug 2020 14:14'	System	05 Aug 2020 22:51:15

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '157.0' cm	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:51:15
DataPoint set to visible.	(b) (4) System	04 Aug 2020 21:05:17

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '76.6' lb	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
DataPoint set to visible.	System	04 Aug 2020 21:05:17

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
Amendment Manager: User entered '14.12560'	System	16 Sep 2020 23:43:01
User entered '14.1'	System	05 Aug 2020 22:51:15
DataPoint set to visible.	System	04 Aug 2020 21:05:17



US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'kg/m2'	System	05 Aug 2020 22:51:15
DataPoint set to visible.	System	04 Aug 2020 21:05:17

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:14
User entered '97.7' F	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:14
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:14
	(b) (4)	
User entered '70'	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'bpm'	System	05 Aug 2020 22:51:15

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:14
User entered '16'	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'breaths/min'	System	05 Aug 2020 22:51:15



US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 19:29:14
User entered '137'	Brianna Burton (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'mmHg'	System	05 Aug 2020 22:51:15

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:14
User entered '81'	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 22:51:15
	(b) (4)	

**US3062075**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User entered 'mmHg'	System	05 Aug 2020 22:51:15

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41

US3062075

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41

US3062075

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:38
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:56:58
	(b) (4)	

US3062075

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	06 Sep 2020 13:15:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 17:53:18
User entered '04 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:38
User entered empty.	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 22:56:58
	(b) (4)	



US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '4 Aug 2020'	Sherry Henning (b) (4)	11 Aug 2020 23:07:45
	(b) (4)	

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	11 Aug 2020 23:07:45
	(b) (4)	

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 07:37:52
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	09 Sep 2020 16:29:54
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:04:26
User entered 'Surgically sterile (SURGICALLY STERILE)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:07:45

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:07:45
	(b) (4)	

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered '01 Jan 1982'	(b) (4) Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:07:45

**US3062075**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:57:41**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	11 Aug 2020 23:07:45
	(b) (4)	

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:07:45

US3062075

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:57:41

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	11 Aug 2020 23:07:45
	(b) (4)	



US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'No (N)'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

**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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

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 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'I'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

US3062075

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 22:57:34
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 21:05:34
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '04 Aug 2020'	Riley King (b) (4)	04 Aug 2020 21:05:34
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[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 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Riley King (b) (4)	04 Aug 2020 21:05:34
	(b) (4)	



US3062075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'VISIT1'	System	04 Aug 2020 21:05:34

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:35:24

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:04:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:04:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 20:35:24
User entered '184664' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:35:24

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 20:35:24

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

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 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:06:40
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

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 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:06:40
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:06:40
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:06:40
	(b) (4)	



US3062075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 21:06:40
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
	(b) (4)	
User entered '157.0' cm	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
	(b) (4)	
User entered '76.6' kg	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
User entered '157.0' cm	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
	(b) (4)	
User entered '76.6' kg	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '4 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	



US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '14:14'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered '4 Aug 2020 14:14'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '97.7' F	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '70'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'bpm'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'breaths/min'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '137'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'mmHg'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '81'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'mmHg'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
User entered '157.0' cm	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:25
	(b) (4)	
User entered '76.6' kg	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	



US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '4 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User closed query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose as it is exactly the same (14:14) and update as appropriate. ' (Site from DM). Query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose as it is exactly the same (14:14) and update as appropriate. ' answered with 'Corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 08:34:09
User entered '16:29' reason for change: Data Entry Error	Jeri King (b) (4)	21 Sep 2020 19:39:12
User opened query 'Per CDM: Per protocol, on Day 1, vital sign measurements should be collected once before IP injection and at least 30 minutes after IP injection. Please review the time of assessment at pre-dose and post-dose as it is exactly the same (14:14) and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:39:03
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)	21 Sep 2020 14:13:07
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).	(b) (4), (b) (6)	12 Aug 2020 06:19:26
User opened 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).	Janna Martinez (b) (4)	05 Aug 2020 23:01:44
User entered '14:14'	(b) (4)	05 Aug 2020 23:01:24
	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered '4 Aug 2020 16:29'	System	21 Sep 2020 19:39:03
User entered '4 Aug 2020 14:14'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '98.7' F	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '66'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'bpm'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '17'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'breaths/min'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '119'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'mmHg'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '75'	Janna Martinez (b) (4)	05 Aug 2020 23:01:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'mmHg'	System	05 Aug 2020 23:01:24

US3062075

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:45
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:03:24
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:29:45
	(b) (4)	
User entered '4 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:03:24
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 21:07:06
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Riley King (b) (4)	04 Aug 2020 21:07:06
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

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 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 21:07:06

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 21:07:06

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '04 Aug 2020'	Riley King (b) (4)	04 Aug 2020 21:07:06
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '15:58'	Riley King (b) (4)	04 Aug 2020 21:07:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered '04 Aug 2020 15:58'	System	04 Aug 2020 21:07:06



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Riley King (b) (4)	04 Aug 2020 21:07:06
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'ONCE'	System	04 Aug 2020 21:07:06

US3062075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 21:07:06

US3062075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:07
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '04 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:04:07
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '15:13'	Janna Martinez (b) (4)	05 Aug 2020 23:04:07
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered '04 Aug 2020 15:13'	System	05 Aug 2020 23:04:07

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '04 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '15:00'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

**US3062075**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered '04 Aug 2020 15:00'	System	05 Aug 2020 23:04:37

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:04:37
	(b) (4)	

US3062075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered empty.	System	05 Aug 2020 23:04:37



US3062075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:04:42
	(b) (4)	

**US3062075**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'I'	System	05 Aug 2020 23:04:42

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:39:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '17c1f981-5573-480b-8324-a09e16d10835' User entered 'Yes (Y)'	System	04 Aug 2020 21:39:58
	System	04 Aug 2020 21:39:58

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:39:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '17c1f981-5573-480b-8324-a09e16d10835' User entered '98.7'	System	04 Aug 2020 21:39:58
	System	04 Aug 2020 21:39:58

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:39:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '17c1f981-5573-480b-8324-a09e16d10835'	System	04 Aug 2020 21:39:58
User entered 'No (N)'	System	04 Aug 2020 21:39:58

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:39:54', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '17c1f981-5573-480b-8324-a09e16d10835'	System	04 Aug 2020 21:39:58
User entered '04 Aug 2020 16:39'	System	04 Aug 2020 21:39:58

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 16:18'	System	04 Aug 2020 21:07:06



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 18:48'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:50:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce97f258-c0da-4686-bca8-603a51530b44'	System	05 Aug 2020 00:52:12
User entered 'Yes (Y)'	System	05 Aug 2020 00:52:12

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:50:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce97f258-c0da-4686-bca8-603a51530b44'	System	05 Aug 2020 00:52:12
User entered '98.4'	System	05 Aug 2020 00:52:12

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:50:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce97f258-c0da-4686-bca8-603a51530b44'	System	05 Aug 2020 00:52:12
User entered 'No (N)'	System	05 Aug 2020 00:52:12

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:52:07', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce97f258-c0da-4686-bca8-603a51530b44'	System	05 Aug 2020 00:52:12
User entered '04 Aug 2020 19:52'	System	05 Aug 2020 00:52:12

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 19:43'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:07:06



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 2'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:21:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6db220e4-1e79-4196-ae1f-c04e7a6fd41c' User entered 'Yes (Y)'	System	05 Aug 2020 23:22:24
	System	05 Aug 2020 23:22:24

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:21:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6db220e4-1e79-4196-ae1f-c04e7a6fd41c' User entered '97.8'	System	05 Aug 2020 23:22:24
	System	05 Aug 2020 23:22:24

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6db220e4-1e79-4196-ae1f-c04e7a6fd41c'	System	05 Aug 2020 23:22:24
User entered 'No (N)'	System	05 Aug 2020 23:22:24

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:21', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6db220e4-1e79-4196-ae1f-c04e7a6fd41c' User entered '05 Aug 2020 18:22'	System	05 Aug 2020 23:22:24
	System	05 Aug 2020 23:22:24

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 3'	System	04 Aug 2020 21:07:06



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:30:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ab2804bd-b10a-4807-81ab-bb673a04ac6c' User entered 'Yes (Y)'	System	07 Aug 2020 02:31:09
	System	07 Aug 2020 02:31:09

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:30:50', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ab2804bd-b10a-4807-81ab-bb673a04ac6c' User entered '97.5'	System	07 Aug 2020 02:31:09
	System	07 Aug 2020 02:31:09

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:30:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ab2804bd-b10a-4807-81ab-bb673a04ac6c' User entered 'No (N)'	System	07 Aug 2020 02:31:09
	System	07 Aug 2020 02:31:09

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:31:07', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ab2804bd-b10a-4807-81ab-bb673a04ac6c' User entered '06 Aug 2020 21:31'	System	07 Aug 2020 02:31:09
	System	07 Aug 2020 02:31:09

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 4'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'c613693d-de95-40f5-b1e7-663f4efa4cc3' User entered 'Yes (Y)'	System	08 Aug 2020 01:51:35
	System	08 Aug 2020 01:51:35



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:19', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'c613693d-de95-40f5-b1e7-663f4efa4cc3' User entered '98.2'	System	08 Aug 2020 01:51:35
	System	08 Aug 2020 01:51:35

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'c613693d-de95-40f5-b1e7-663f4efa4cc3'	System	08 Aug 2020 01:51:35
User entered 'No (N)'	System	08 Aug 2020 01:51:35

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'c613693d-de95-40f5-b1e7-663f4efa4cc3' User entered '07 Aug 2020 20:51'	System	08 Aug 2020 01:51:35
	System	08 Aug 2020 01:51:35

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 5'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:35:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '85670e79-b144-426e-9243-13d54f55d16e' User entered 'Yes (Y)'	System	09 Aug 2020 02:37:39
	System	09 Aug 2020 02:37:39

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:37:16', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '85670e79-b144-426e-9243-13d54f55d16e' User entered '97.0'	System	09 Aug 2020 02:37:39
	System	09 Aug 2020 02:37:39



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:37:22', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '85670e79-b144-426e-9243-13d54f55d16e' User entered 'No (N)'	System	09 Aug 2020 02:37:39
	System	09 Aug 2020 02:37:39

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:37:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '85670e79-b144-426e-9243-13d54f55d16e' User entered '08 Aug 2020 21:37'	System	09 Aug 2020 02:37:39
	System	09 Aug 2020 02:37:39

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 6'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '655e5ed6-908e-44fc-8f3e-752cd9b120ae' User entered 'Yes (Y)'	System	09 Aug 2020 23:54:38
	System	09 Aug 2020 23:54:38

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:15', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '655e5ed6-908e-44fc-8f3e-752cd9b120ae' User entered '98.3'	System	09 Aug 2020 23:54:38
	System	09 Aug 2020 23:54:38

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:25', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '655e5ed6-908e-44fc-8f3e-752cd9b120ae' User entered 'No (N)'	System	09 Aug 2020 23:54:38
	System	09 Aug 2020 23:54:38



**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '655e5ed6-908e-44fc-8f3e-752cd9b120ae' User entered '09 Aug 2020 18:54'	System	09 Aug 2020 23:54:38
	System	09 Aug 2020 23:54:38

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 7'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:53:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a6c43c23-d5cc-4c40-a37a-2385f9c76560' User entered 'Yes (Y)'	System	10 Aug 2020 21:54:19
	System	10 Aug 2020 21:54:19

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a6c43c23-d5cc-4c40-a37a-2385f9c76560' User entered '98.5'	System	10 Aug 2020 21:54:19
	System	10 Aug 2020 21:54:19

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:11', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a6c43c23-d5cc-4c40-a37a-2385f9c76560'	System	10 Aug 2020 21:54:19
User entered 'No (N)'	System	10 Aug 2020 21:54:19

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a6c43c23-d5cc-4c40-a37a-2385f9c76560'	System	10 Aug 2020 21:54:19
User entered '10 Aug 2020 16:54'	System	10 Aug 2020 21:54:19



US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:40:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '97882e01-11b9-4554-9688-3de335f2c1c0' User entered 'None (1)'	System	04 Aug 2020 21:41:39
	System	04 Aug 2020 21:41:39

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:40:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '97882e01-11b9-4554-9688-3de335f2c1c0' User entered 'No (N)'	System	04 Aug 2020 21:41:39
	System	04 Aug 2020 21:41:39

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:40:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '97882e01-11b9-4554-9688-3de335f2c1c0' User entered 'No (N)'	System	04 Aug 2020 21:41:39
	System	04 Aug 2020 21:41:39

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:41:02', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '97882e01-11b9-4554-9688-3de335f2c1c0' User entered 'None (1)'	System	04 Aug 2020 21:41:39
	System	04 Aug 2020 21:41:39

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:41:36', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '97882e01-11b9-4554-9688-3de335f2c1c0' User entered '04 Aug 2020 16:41'	System	04 Aug 2020 21:41:39
	System	04 Aug 2020 21:41:39



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 16:18'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 18:48'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:52:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd8a14e50-d14a-4f05-893e-374ae8a3258c' User entered 'None (1)'	System	05 Aug 2020 00:53:18
	System	05 Aug 2020 00:53:18

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:52:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd8a14e50-d14a-4f05-893e-374ae8a3258c' User entered 'No (N)'	System	05 Aug 2020 00:53:18
	System	05 Aug 2020 00:53:18

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:52:41', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd8a14e50-d14a-4f05-893e-374ae8a3258c' User entered 'No (N)'	System	05 Aug 2020 00:53:18
	System	05 Aug 2020 00:53:18

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:52:54', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd8a14e50-d14a-4f05-893e-374ae8a3258c' User entered 'None (1)'	System	05 Aug 2020 00:53:18
	System	05 Aug 2020 00:53:18

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:53:16', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd8a14e50-d14a-4f05-893e-374ae8a3258c' User entered '04 Aug 2020 19:53'	System	05 Aug 2020 00:53:18
	System	05 Aug 2020 00:53:18



**US3062075**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 19:43'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 2'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:40', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '46b3b17f-2d91-4ebe-b28a-2332aa7e0429'	System	05 Aug 2020 23:23:16
User entered 'None (1)'	System	05 Aug 2020 23:23:16

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:45', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '46b3b17f-2d91-4ebe-b28a-2332aa7e0429' User entered 'No (N)'	System	05 Aug 2020 23:23:16
	System	05 Aug 2020 23:23:16

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:50', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '46b3b17f-2d91-4ebe-b28a-2332aa7e0429' User entered 'No (N)'	System	05 Aug 2020 23:23:16
	System	05 Aug 2020 23:23:16

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:22:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '46b3b17f-2d91-4ebe-b28a-2332aa7e0429' User entered 'None (1)'	System	05 Aug 2020 23:23:16
	System	05 Aug 2020 23:23:16

**US3062075**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '46b3b17f-2d91-4ebe-b28a-2332aa7e0429' User entered '05 Aug 2020 18:23'	System	05 Aug 2020 23:23:16
	System	05 Aug 2020 23:23:16



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 3'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:31:43', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e406e33-1c80-4fa5-a2ae-f33226b95f11' User entered 'None (1)'	System	07 Aug 2020 02:32:27
	System	07 Aug 2020 02:32:27

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:31:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e406e33-1c80-4fa5-a2ae-f33226b95f11' User entered 'No (N)'	System	07 Aug 2020 02:32:27
	System	07 Aug 2020 02:32:27

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:31:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e406e33-1c80-4fa5-a2ae-f33226b95f11' User entered 'No (N)'	System	07 Aug 2020 02:32:27
	System	07 Aug 2020 02:32:27

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e406e33-1c80-4fa5-a2ae-f33226b95f11' User entered 'None (1)'	System	07 Aug 2020 02:32:27
	System	07 Aug 2020 02:32:27

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e406e33-1c80-4fa5-a2ae-f33226b95f11' User entered '06 Aug 2020 21:32'	System	07 Aug 2020 02:32:27
	System	07 Aug 2020 02:32:27



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 4'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:48:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2357722b-cc75-46e8-9fe5-e7fe4d1b0f3d' User entered 'None (1)'	System	08 Aug 2020 01:51:05
	System	08 Aug 2020 01:51:05

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:48:05', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2357722b-cc75-46e8-9fe5-e7fe4d1b0f3d' User entered 'No (N)'	System	08 Aug 2020 01:51:05
	System	08 Aug 2020 01:51:05

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:48:12', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2357722b-cc75-46e8-9fe5-e7fe4d1b0f3d' User entered 'No (N)'	System	08 Aug 2020 01:51:05
	System	08 Aug 2020 01:51:05

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:48:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2357722b-cc75-46e8-9fe5-e7fe4d1b0f3d' User entered 'None (1)'	System	08 Aug 2020 01:51:05
	System	08 Aug 2020 01:51:05

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:50:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2357722b-cc75-46e8-9fe5-e7fe4d1b0f3d' User entered '07 Aug 2020 20:50'	System	08 Aug 2020 01:51:05
	System	08 Aug 2020 01:51:05



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 5'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:25', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '826aafdd-2172-4185-bf57-315aad821b21'	System	09 Aug 2020 02:38:44
User entered 'None (1)'	System	09 Aug 2020 02:38:44

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:05', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '826aafdd-2172-4185-bf57-315aad821b21' User entered 'No (N)'	System	09 Aug 2020 02:38:44
	System	09 Aug 2020 02:38:44

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:12', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '826aafdd-2172-4185-bf57-315aad821b21' User entered 'No (N)'	System	09 Aug 2020 02:38:44
	System	09 Aug 2020 02:38:44

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:17', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '826aafdd-2172-4185-bf57-315aad821b21' User entered 'None (1)'	System	09 Aug 2020 02:38:44
	System	09 Aug 2020 02:38:44

**US3062075**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:41', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '826aafdd-2172-4185-bf57-315aad821b21' User entered '08 Aug 2020 21:38'	System	09 Aug 2020 02:38:44
	System	09 Aug 2020 02:38:44



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 6'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0355bdf-9a76-433b-9b6a-1b15a55e9e34'	System	09 Aug 2020 23:55:22
User entered 'None (1)'	System	09 Aug 2020 23:55:22

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0355bdf-9a76-433b-9b6a-1b15a55e9e34'	System	09 Aug 2020 23:55:22
User entered 'No (N)'	System	09 Aug 2020 23:55:22

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0355bdf-9a76-433b-9b6a-1b15a55e9e34'	System	09 Aug 2020 23:55:22
User entered 'No (N)'	System	09 Aug 2020 23:55:22

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:54:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0355bdf-9a76-433b-9b6a-1b15a55e9e34'	System	09 Aug 2020 23:55:22
User entered 'None (1)'	System	09 Aug 2020 23:55:22

**US3062075**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:55:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0355bdf-9a76-433b-9b6a-1b15a55e9e34' User entered '09 Aug 2020 18:55'	System	09 Aug 2020 23:55:22
	System	09 Aug 2020 23:55:22



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 7'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:25', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93f6072a-e8e0-4ac0-b8c0-4f91aa709c7a'	System	10 Aug 2020 21:54:58
User entered 'None (1)'	System	10 Aug 2020 21:54:58

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93f6072a-e8e0-4ac0-b8c0-4f91aa709c7a' User entered 'No (N)'	System	10 Aug 2020 21:54:58
	System	10 Aug 2020 21:54:58

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93f6072a-e8e0-4ac0-b8c0-4f91aa709c7a' User entered 'No (N)'	System	10 Aug 2020 21:54:58
	System	10 Aug 2020 21:54:58

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:45', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93f6072a-e8e0-4ac0-b8c0-4f91aa709c7a' User entered 'None (1)'	System	10 Aug 2020 21:54:58
	System	10 Aug 2020 21:54:58

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:54:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93f6072a-e8e0-4ac0-b8c0-4f91aa709c7a' User entered '10 Aug 2020 16:54'	System	10 Aug 2020 21:54:58
	System	10 Aug 2020 21:54:58



US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:41:48', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:41:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:12', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:19', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'None (0)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:36', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered 'No (N)'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

**US3062075**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T16:42:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9e5559cc-4e37-466e-9aae-9e493e6153b6' User entered '04 Aug 2020 16:42'	System	04 Aug 2020 21:43:02
	System	04 Aug 2020 21:43:02

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 16:18'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 18:48'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

**US3062075**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'None (0)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:46:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered 'No (N)'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

**US3062075**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-04T19:47:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4590ec82-0c26-4a69-b0b8-e177dbdf51ac' User entered '04 Aug 2020 19:47'	System	05 Aug 2020 00:47:56
	System	05 Aug 2020 00:47:56

**US3062075**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Aug 2020 19:43'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:07:06



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 2'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:32', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:39', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'None (0)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:23:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered 'No (N)'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09



**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-05T18:24:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '5616c9f9-5e8f-4d67-ad8b-bb078ce9c04b' User entered '05 Aug 2020 18:24'	System	05 Aug 2020 23:24:09
	System	05 Aug 2020 23:24:09

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 3'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:43', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12



**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:32:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'None (0)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:33:04', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered 'No (N)'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-06T21:33:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2657b49a-b590-49bd-80c5-552e83b3afa7' User entered '06 Aug 2020 21:33'	System	07 Aug 2020 02:33:12
	System	07 Aug 2020 02:33:12

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 4'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:48', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:52', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:51:59', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:52:03', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'None (0)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:52:07', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered 'No (N)'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-07T20:52:28', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd003bf6c-5217-4191-9d21-6c9b421e62d9' User entered '07 Aug 2020 20:52'	System	08 Aug 2020 01:52:29
	System	08 Aug 2020 01:52:29

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:07:06



**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 5'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:38:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:39:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:39:04', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'None (0)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:39:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered 'No (N)'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-08T21:39:36', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0b867aa2-be53-4304-a0f5-e3aee373844f' User entered '08 Aug 2020 21:39'	System	09 Aug 2020 02:39:38
	System	09 Aug 2020 02:39:38

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 6'	System	04 Aug 2020 21:07:06

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:55:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:55:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:55:55', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:56:01', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:56:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:56:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'None (0)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:56:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered 'No (N)'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-09T18:57:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e6b648b-88b6-435f-b815-e9715c47e1c6' User entered '09 Aug 2020 18:57'	System	09 Aug 2020 23:57:34
	System	09 Aug 2020 23:57:34

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 7'	System	04 Aug 2020 21:07:06



US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:02', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:15', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'None (0)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

US3062075

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered 'No (N)'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-08-10T16:55:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '265bdab9-d168-433a-9e0f-283d4775c154' User entered '10 Aug 2020 16:55'	System	10 Aug 2020 21:55:37
	System	10 Aug 2020 21:55:37



**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:07:06

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	13 Aug 2020 16:56:18
	(b) (4)	

US3062075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '12 Aug 2020'	Janna Martinez (b) (4)	13 Aug 2020 16:56:18
	(b) (4)	

US3062075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	13 Aug 2020 16:56:18
	(b) (4)	

US3062075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered empty.	(b) (4) Janna Martinez (b) (4)	13 Aug 2020 16:56:18
	(b) (4)	

US3062075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	13 Aug 2020 16:56:06
	(b) (4)	

US3062075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'I'	System	13 Aug 2020 16:56:06



US3062075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:56:58
	(b) (4)	

US3062075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '19 Aug 2020'	Janna Martinez (b) (4)	19 Aug 2020 19:56:58
	(b) (4)	

US3062075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	19 Aug 2020 19:56:58
	(b) (4)	

US3062075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	19 Aug 2020 19:56:58
	(b) (4)	

US3062075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:56:45
	(b) (4)	

**US3062075**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:48
User entered 'I'	System	19 Aug 2020 19:56:45

US3062075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	26 Aug 2020 22:21:35
	(b) (4)	

US3062075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered '26 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 22:21:35



US3062075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	26 Aug 2020 22:21:35

US3062075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered empty.	(b) (4) Janna Martinez (b) (4)	26 Aug 2020 22:21:35
	(b) (4)	

US3062075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 22:19:19

**US3062075**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:49:39
User entered 'I'	System	26 Aug 2020 22:19:19

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Sep 2020 17:53:18
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '1 Sep 2020'	Sherry Henning (b) (4)	01 Sep 2020 17:53:18
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[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 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	01 Sep 2020 17:53:18
	(b) (4)	

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'VISIT2'	System	01 Sep 2020 17:53:18



US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '1 Sep 2020'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '11:42'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1 Sep 2020 11:42'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '97.2' F	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	



US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '109'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'bpm'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '16'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'breaths/min'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '109'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '76'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	01 Sep 2020 20:05:11



US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '1 Sep 2020'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '13:18'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1 Sep 2020 13:18'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '98.0' F	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	



US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '66'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'bpm'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered '16'	(b) (4) Colton King (b) (4) (b) (4)	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'breaths/min'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '122'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	01 Sep 2020 20:05:11

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '69'	Colton King (b) (4)	01 Sep 2020 20:05:11
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	01 Sep 2020 20:05:11



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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:12:38
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '1 Sep 2020'	Colton King (b) (4)	01 Sep 2020 20:12:38
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

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 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:55:37

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '1 Sep 2020'	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '12:47'	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1 Sep 2020 12:47'	System	01 Sep 2020 17:55:37

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	01 Sep 2020 17:55:37
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'ONCE'	System	01 Sep 2020 17:55:37

US3062075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:55:37

US3062075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:11:54
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:50:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'V2 is correct. Site had to use unscheduled kits in place of V2 due to inadequate supply. ' (Site from DM).	marissa Mueller (b) (4)	19 Oct 2020 14:38:15
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 01SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:25:39
User entered '1 Sep 2020'	Colton King (b) (4)	01 Sep 2020 20:11:54
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '11:55'	Colton King (b) (4)	01 Sep 2020 20:11:54
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1 Sep 2020 11:55'	System	01 Sep 2020 20:11:54



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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User closed query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 01SEP2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 01SEP2020 or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 23:19:36
Query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 01SEP2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 01SEP2020 or clarify. ' answered with 'THERE WAS A SPACE BETWEEN AMENDMENTS WHERE SITE DIDNT HAVE APPROPRIATE KITS AND WAS ADVISED TO USE UNSCHEUDLED TO FULFILL NEEDED VISIT 2 LAB REQUIREMENTS.' (Site from DM).	Janna Martinez (b) (4) (b) (4)	29 Oct 2020 18:11:25
User opened query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 01SEP2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 01SEP2020 or clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 10:56:14
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(01SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:13:18
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(01SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:02:25
User entered '1 Sep 2020'	Colton King (b) (4) (b) (4)	01 Sep 2020 20:12:12

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EAB) (1725)

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**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	01 Sep 2020 20:12:12

US3062075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:12:12
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '12:00'	Colton King (b) (4)	01 Sep 2020 20:12:12
	(b) (4)	

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1 Sep 2020 12:00'	System	01 Sep 2020 20:12:12

**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	01 Sep 2020 20:12:12

US3062075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	01 Sep 2020 20:12:12
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Colton King (b) (4)	01 Sep 2020 20:12:12
	(b) (4)	



**US3062075**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered empty.	System	01 Sep 2020 20:12:12

US3062075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	01 Sep 2020 20:12:24
	(b) (4)	

US3062075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	01 Sep 2020 20:12:24

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:25:28', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93a81e0f-182b-4314-a04b-6a117c8536c9' User entered 'Yes (Y)'	System	01 Sep 2020 18:26:06
	System	01 Sep 2020 18:26:06

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:25:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93a81e0f-182b-4314-a04b-6a117c8536c9' User entered '98.0'	System	01 Sep 2020 18:26:06
	System	01 Sep 2020 18:26:06

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:25:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93a81e0f-182b-4314-a04b-6a117c8536c9' User entered 'No (N)'	System	01 Sep 2020 18:26:06
	System	01 Sep 2020 18:26:06

**US3062075**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:26:03', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '93a81e0f-182b-4314-a04b-6a117c8536c9'	System	01 Sep 2020 18:26:06
User entered '01 Sep 2020 13:26'	System	01 Sep 2020 18:26:06



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:10:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '98bd6bb6-f392-4072-b4bd-3ca282edc2a7' User entered 'Yes (Y)'	System	02 Sep 2020 13:11:42
	System	02 Sep 2020 13:11:42

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:11:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '98bd6bb6-f392-4072-b4bd-3ca282edc2a7' User entered '97.7'	System	02 Sep 2020 13:11:42
	System	02 Sep 2020 13:11:42

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:11:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '98bd6bb6-f392-4072-b4bd-3ca282edc2a7'	System	02 Sep 2020 13:11:42
User entered 'No (N)'	System	02 Sep 2020 13:11:42

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:11:39', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '98bd6bb6-f392-4072-b4bd-3ca282edc2a7' User entered '02 Sep 2020 08:11'	System	02 Sep 2020 13:11:42
	System	02 Sep 2020 13:11:42

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 2'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:52:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '22aab4e4-5374-442c-9acb-737bc9c5256b' User entered 'Yes (Y)'	System	03 Sep 2020 01:53:44
	System	03 Sep 2020 01:53:44

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:52:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '22aab4e4-5374-442c-9acb-737bc9c5256b' User entered '97.2'	System	03 Sep 2020 01:53:44
	System	03 Sep 2020 01:53:44

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:52:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '22aab4e4-5374-442c-9acb-737bc9c5256b' User entered 'No (N)'	System	03 Sep 2020 01:53:44
	System	03 Sep 2020 01:53:44

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:52:59', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '22aab4e4-5374-442c-9acb-737bc9c5256b' User entered '02 Sep 2020 20:52'	System	03 Sep 2020 01:53:44
	System	03 Sep 2020 01:53:44

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 3'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:09', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e3663dcb-c5a1-48fa-a37c-91a633881eda' User entered 'Yes (Y)'	System	04 Sep 2020 03:47:37
	System	04 Sep 2020 03:47:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:19', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e3663dcb-c5a1-48fa-a37c-91a633881eda' User entered '96.5'	System	04 Sep 2020 03:47:37
	System	04 Sep 2020 03:47:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e3663dcb-c5a1-48fa-a37c-91a633881eda' User entered 'No (N)'	System	04 Sep 2020 03:47:37
	System	04 Sep 2020 03:47:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:32', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e3663dcB-c5a1-48fa-a37c-91a633881eda' User entered '03 Sep 2020 22:47'	System	04 Sep 2020 03:47:37
	System	04 Sep 2020 03:47:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 4'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:06:35', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6497a00b-9d34-4ca5-9135-3816533e5459' User entered 'Yes (Y)'	System	05 Sep 2020 03:07:01
	System	05 Sep 2020 03:07:01

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:06:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6497a00b-9d34-4ca5-9135-3816533e5459' User entered '97.2'	System	05 Sep 2020 03:07:01
	System	05 Sep 2020 03:07:01

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:06:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6497a00b-9d34-4ca5-9135-3816533e5459' User entered 'No (N)'	System	05 Sep 2020 03:07:01
	System	05 Sep 2020 03:07:01

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:06:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6497a00b-9d34-4ca5-9135-3816533e5459' User entered '04 Sep 2020 22:06'	System	05 Sep 2020 03:07:01
	System	05 Sep 2020 03:07:01

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 5'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:51:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c' User entered 'Yes (Y)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:51:50', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c' User entered '98.2'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:51:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c' User entered 'Yes (Y)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at next TX ' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 06:56:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	marissa Mueller (b) (4)	08 Sep 2020 16:43:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:52:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c'	(b) (4)	
User entered '1'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:52:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c' User entered '0'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:52:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '540fa046-2443-4def-84aa-5aa539ea6e2c' User entered '05 Sep 2020 20:52'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 6'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:25:28', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9bb3f69a-0ac2-4352-9d78-9235b0c2f4e5' User entered 'Yes (Y)'	System	08 Sep 2020 15:44:20
	System	08 Sep 2020 15:44:20

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:25:35', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9bb3f69a-0ac2-4352-9d78-9235b0c2f4e5' User entered '98.4'	System	08 Sep 2020 15:44:20
	System	08 Sep 2020 15:44:20

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:25:43', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9bb3f69a-0ac2-4352-9d78-9235b0c2f4e5' User entered 'No (N)'	System	08 Sep 2020 15:44:20
	System	08 Sep 2020 15:44:20

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:25:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9bb3f69a-0ac2-4352-9d78-9235b0c2f4e5' User entered '06 Sep 2020 22:25'	System	08 Sep 2020 15:44:20
	System	08 Sep 2020 15:44:20

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 7'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:44:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'beb6c58d-04ad-4618-bb9f-0d7be726aa83' User entered 'Yes (Y)'	System	08 Sep 2020 15:46:47
	System	08 Sep 2020 15:46:47



US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:44:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'beb6c58d-04ad-4618-bb9f-0d7be726aa83' User entered '99.0'	System	08 Sep 2020 15:46:47
	System	08 Sep 2020 15:46:47

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:46:35', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'beb6c58d-04ad-4618-bb9f-0d7be726aa83' User entered 'No (N)'	System	08 Sep 2020 15:46:47
	System	08 Sep 2020 15:46:47

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:46:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'beb6c58d-04ad-4618-bb9f-0d7be726aa83' User entered '08 Sep 2020 10:46'	System	08 Sep 2020 15:46:47
	System	08 Sep 2020 15:46:47

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:26:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd0171324-df0f-4a7f-b293-6dee3e4f7110'	System	01 Sep 2020 18:29:26
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 18:29:26

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:28:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd0171324-df0f-4a7f-b293-6dee3e4f7110' User entered 'No (N)'	System	01 Sep 2020 18:29:26
	System	01 Sep 2020 18:29:26



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:26:41', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd0171324-df0f-4a7f-b293-6dee3e4f7110'	System	01 Sep 2020 18:29:26
User entered 'No (N)'	System	01 Sep 2020 18:29:26

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:27:02', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd0171324-df0f-4a7f-b293-6dee3e4f7110'	System	01 Sep 2020 18:29:26
User entered 'None (1)'	System	01 Sep 2020 18:29:26

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:29:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd0171324-df0f-4a7f-b293-6dee3e4f7110' User entered '01 Sep 2020 13:29'	System	01 Sep 2020 18:29:26
	System	01 Sep 2020 18:29:26

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:22:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9c70deaa-44d0-43f8-abcd-60ad46d588db' User entered 'None (1)'	System	02 Sep 2020 13:23:12
	System	02 Sep 2020 13:23:12

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:21:15', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9c70deaa-44d0-43f8-abcd-60ad46d588db' User entered 'No (N)'	System	02 Sep 2020 13:23:12
	System	02 Sep 2020 13:23:12



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:12:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9c70deaa-44d0-43f8-abcd-60ad46d588db' User entered 'No (N)'	System	02 Sep 2020 13:23:12
	System	02 Sep 2020 13:23:12

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:19:48', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9c70deaa-44d0-43f8-abcd-60ad46d588db' User entered 'None (1)'	System	02 Sep 2020 13:23:12
	System	02 Sep 2020 13:23:12

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9c70deaa-44d0-43f8-abcd-60ad46d588db' User entered '02 Sep 2020 08:23'	System	02 Sep 2020 13:23:12
	System	02 Sep 2020 13:23:12

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 2'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:16', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '51939593-73e6-448f-b9fa-bced12187ee3' User entered 'None (1)'	System	03 Sep 2020 01:54:08
	System	03 Sep 2020 01:54:08

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:20', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '51939593-73e6-448f-b9fa-bced12187ee3' User entered 'No (N)'	System	03 Sep 2020 01:54:08
	System	03 Sep 2020 01:54:08



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '51939593-73e6-448f-b9fa-bced12187ee3' User entered 'No (N)'	System	03 Sep 2020 01:54:08
	System	03 Sep 2020 01:54:08

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '51939593-73e6-448f-b9fa-bced12187ee3' User entered 'None (1)'	System	03 Sep 2020 01:54:08
	System	03 Sep 2020 01:54:08

**US3062075**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:45', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '51939593-73e6-448f-b9fa-bced12187ee3' User entered '02 Sep 2020 20:53'	System	03 Sep 2020 01:54:08
	System	03 Sep 2020 01:54:08

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 3'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:52', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'db784bc0-1b02-4f8b-865b-1432ccd26f9c' User entered 'None (1)'	System	04 Sep 2020 03:48:21
	System	04 Sep 2020 03:48:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:48', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'db784bc0-1b02-4f8b-865b-1432ccd26f9c' User entered 'No (N)'	System	04 Sep 2020 03:48:21
	System	04 Sep 2020 03:48:21



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:47:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'db784bc0-1b02-4f8b-865b-1432ccd26f9c' User entered 'No (N)'	System	04 Sep 2020 03:48:21
	System	04 Sep 2020 03:48:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:02', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'db784bc0-1b02-4f8b-865b-1432ccd26f9c' User entered 'None (1)'	System	04 Sep 2020 03:48:21
	System	04 Sep 2020 03:48:21

**US3062075**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:19', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'db784bc0-1b02-4f8b-865b-1432ccd26f9c' User entered '03 Sep 2020 22:48'	System	04 Sep 2020 03:48:21
	System	04 Sep 2020 03:48:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 4'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8e097eab-d8a6-4ec2-8dd1-1458fc3e1da4'	System	05 Sep 2020 03:07:29
User entered 'None (1)'	System	05 Sep 2020 03:07:29

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8e097eab-d8a6-4ec2-8dd1-1458fc3e1da4' User entered 'No (N)'	System	05 Sep 2020 03:07:29
	System	05 Sep 2020 03:07:29



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8e097eab-d8a6-4ec2-8dd1-1458fc3e1da4' User entered 'No (N)'	System	05 Sep 2020 03:07:29
	System	05 Sep 2020 03:07:29

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8e097eab-d8a6-4ec2-8dd1-1458fc3e1da4' User entered 'None (1)'	System	05 Sep 2020 03:07:29
	System	05 Sep 2020 03:07:29

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8e097eab-d8a6-4ec2-8dd1-1458fc3e1da4' User entered '04 Sep 2020 22:07'	System	05 Sep 2020 03:07:29
	System	05 Sep 2020 03:07:29

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 5'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:52:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce910e5c-f804-4681-a8cf-2c6885ef2b87' User entered 'None (1)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:52:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce910e5c-f804-4681-a8cf-2c6885ef2b87' User entered 'No (N)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce910e5c-f804-4681-a8cf-2c6885ef2b87' User entered 'No (N)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce910e5c-f804-4681-a8cf-2c6885ef2b87' User entered 'None (1)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

**US3062075**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ce910e5c-f804-4681-a8cf-2c6885ef2b87' User entered '05 Sep 2020 20:53'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 6'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:04', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '92fe745e-f397-424c-89c1-4a09c4b2370b' User entered 'None (1)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:09', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '92fe745e-f397-424c-89c1-4a09c4b2370b' User entered 'No (N)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '92fe745e-f397-424c-89c1-4a09c4b2370b' User entered 'No (N)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:16', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '92fe745e-f397-424c-89c1-4a09c4b2370b' User entered 'None (1)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

**US3062075**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '92fe745e-f397-424c-89c1-4a09c4b2370b' User entered '06 Sep 2020 22:26'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 7'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:46:59', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bfaebcc7-df38-47ff-8cde-2308581ce0a0' User entered 'None (1)'	System	08 Sep 2020 15:47:44
	System	08 Sep 2020 15:47:44

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:47:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bfaebcc7-df38-47ff-8cde-2308581ce0a0' User entered 'No (N)'	System	08 Sep 2020 15:47:44
	System	08 Sep 2020 15:47:44



US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:47:22', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bfaebcc7-df38-47ff-8cde-2308581ce0a0' User entered 'No (N)'	System	08 Sep 2020 15:47:44
	System	08 Sep 2020 15:47:44

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:47:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bfaebcc7-df38-47ff-8cde-2308581ce0a0'	System	08 Sep 2020 15:47:44
User entered 'None (1)'	System	08 Sep 2020 15:47:44

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:47:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bfaebcc7-df38-47ff-8cde-2308581ce0a0' User entered '08 Sep 2020 10:47'	System	08 Sep 2020 15:47:44
	System	08 Sep 2020 15:47:44

US3062075

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:32:05', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b'	System	01 Sep 2020 18:32:53
User entered 'No interference with activity (1)'	System	01 Sep 2020 18:32:53

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:32:11', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b'	System	01 Sep 2020 18:32:53
User entered 'No interference with activity (1)'	System	01 Sep 2020 18:32:53



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:32:22', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b' User entered 'No interference with activity (1)'	System	01 Sep 2020 18:32:53
	System	01 Sep 2020 18:32:53

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:32:33', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b' User entered 'No interference with activity (1)'	System	01 Sep 2020 18:32:53
	System	01 Sep 2020 18:32:53

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:31:09', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b'	System	01 Sep 2020 18:32:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Sep 2020 18:32:53

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:31:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b'	System	01 Sep 2020 18:32:53
User entered 'No interference with activity (1)'	System	01 Sep 2020 18:32:53

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:31:21', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b' User entered 'No (N)'	System	01 Sep 2020 18:32:53
	System	01 Sep 2020 18:32:53

**US3062075**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-01T13:32:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '1e07cf97-d977-4aed-91f4-029471f20d8b' User entered '01 Sep 2020 13:32'	System	01 Sep 2020 18:32:53
	System	01 Sep 2020 18:32:53

**US3062075**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:25:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:23:54', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'None (0)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:24:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered 'No (N)'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00



**US3062075**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T08:25:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '949dc320-7646-4b95-8526-c503e8ef9361' User entered '02 Sep 2020 08:25'	System	02 Sep 2020 13:26:00
	System	02 Sep 2020 13:26:00

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:55:37

**US3062075**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 2'	System	01 Sep 2020 17:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:53:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:07', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:12', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:15', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:18', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97' User entered 'None (0)'	System	04 Sep 2020 03:47:10
	System	04 Sep 2020 03:47:10

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:24', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97'	System	04 Sep 2020 03:47:10
User entered 'No (N)'	System	04 Sep 2020 03:47:10

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-02T20:54:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'b0159bd3-ff05-4403-b7b0-9adfd0eb6c97'	System	04 Sep 2020 03:47:10
User entered '02 Sep 2020 20:54'	System	04 Sep 2020 03:47:10

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 3'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'None (0)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:48:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered 'No (N)'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-03T22:49:03', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8c922258-bf86-4f14-b812-9de6ce25b924' User entered '03 Sep 2020 22:49'	System	04 Sep 2020 03:49:07
	System	04 Sep 2020 03:49:07

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:55:37



**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 4'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:42', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:59', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:07:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:08:02', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'None (0)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:08:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered 'No (N)'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-04T22:08:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4cebc0f6-da48-4e88-b3ed-8eb630b1d14b' User entered '04 Sep 2020 22:08'	System	05 Sep 2020 03:08:17
	System	05 Sep 2020 03:08:17

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 5'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:54', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:53:59', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:54:07', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:54:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:54:19', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'None (0)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:54:25', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered 'No (N)'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-05T20:54:30', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '0ee0367c-4f80-4f10-866e-164c28468efb' User entered '05 Sep 2020 20:54'	System	08 Sep 2020 15:44:19
	System	08 Sep 2020 15:44:19

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:57:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 6'	System	01 Sep 2020 17:55:37



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:33', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:40', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:43', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:26:57', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337' User entered 'None (0)'	System	08 Sep 2020 15:44:21
	System	08 Sep 2020 15:44:21

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:27:03', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337'	System	08 Sep 2020 15:44:21
User entered 'No (N)'	System	08 Sep 2020 15:44:21

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-06T22:27:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '6f47a35a-4c38-473c-b4e7-0dfb1675f337'	System	08 Sep 2020 15:44:21
User entered '06 Sep 2020 22:27'	System	08 Sep 2020 15:44:21



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:57:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	01 Sep 2020 17:55:37
User entered 'Day 7'	System	01 Sep 2020 17:55:37

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:48:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:34', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52



US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:40', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'None (0)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

US3062075

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:43', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered 'No (N)'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-09-08T10:49:50', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '95e0d62a-aac6-4a87-9b5e-10c46cc4cadb' User entered '08 Sep 2020 10:49'	System	08 Sep 2020 15:49:52
	System	08 Sep 2020 15:49:52

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:55:37

**US3062075**

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

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

**Generated On: 09 Jun 2021 14:57:41**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:55:37

**US3062075**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 19:45:58
	(b) (4)	

**US3062075**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 19:45:58
	(b) (4)	

US3062075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	08 Sep 2020 19:45:58
	(b) (4)	



US3062075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered empty.	Colton King (b) (4)	08 Sep 2020 19:45:58
	(b) (4)	

US3062075

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 19:46:02
	(b) (4)	

**US3062075**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	08 Sep 2020 19:46:02

US3062075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	15 Sep 2020 21:13:56
	(b) (4)	

US3062075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered '15 Sep 2020'	Colton King (b) (4)	15 Sep 2020 21:13:56
	(b) (4)	

US3062075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	15 Sep 2020 21:13:56
	(b) (4)	

US3062075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered empty.	Colton King (b) (4)	15 Sep 2020 21:13:56
	(b) (4)	

US3062075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 21:14:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 21:14:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	15 Sep 2020 21:14:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 21:14:01
User entered empty.	Colton King (b) (4)	15 Sep 2020 21:14:01
	(b) (4)	



**US3062075**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '1'	System	15 Sep 2020 21:14:05
User entered empty.	System	15 Sep 2020 21:14:01

**US3062075**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 16:08:54
	(b) (4)	

**US3062075**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
User entered '22 Sep 2020'	(b) (4) Colton King (b) (4) (b) (4)	22 Sep 2020 16:08:54

US3062075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	22 Sep 2020 16:08:54
	(b) (4)	

US3062075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered empty.	Colton King (b) (4)	22 Sep 2020 16:08:54
	(b) (4)	

US3062075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:00
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:03:18
	(b) (4)	

US3062075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	26 Sep 2020 19:03:18

**US3062075**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	26 Sep 2020 19:04:52
	(b) (4)	



**US3062075**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:04:52
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[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 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Home (Home)'	Janna Martinez (b) (4)	26 Sep 2020 19:04:52
	(b) (4)	

**US3062075**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'VISIT3'	System	26 Sep 2020 19:04:52

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '11:38'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

**US3062075**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '26 Sep 2020 11:38'	System	26 Sep 2020 19:05:37

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '98.8' F	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	



US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

**US3062075**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '67'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

**US3062075**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'bpm'	System	26 Sep 2020 19:05:37

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'breaths/min'	System	26 Sep 2020 19:05:37

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '141'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	26 Sep 2020 19:05:37



US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '87'	Janna Martinez (b) (4)	26 Sep 2020 19:05:37
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	26 Sep 2020 19:05:37

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03

US3062075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03

US3062075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	26 Sep 2020 19:05:41
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	26 Sep 2020 19:05:41
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:05:58
	(b) (4)	

US3062075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:05:58
	(b) (4)	



US3062075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered '11:50'	Janna Martinez (b) (4)	26 Sep 2020 19:05:58
	(b) (4)	

**US3062075**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '26 Sep 2020 11:50'	System	26 Sep 2020 19:05:58

US3062075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:06:01
	(b) (4)	

**US3062075**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	26 Sep 2020 19:06:01

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 64'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

[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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-05T11:46:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2243066b-22e4-4d3f-bece-fda41ee9c246'	System	05 Oct 2020 16:47:04
User entered 'No (N)'	System	05 Oct 2020 16:47:04

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-05T11:46:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2243066b-22e4-4d3f-bece-fda41ee9c246'	System	05 Oct 2020 16:47:04
User entered 'No (N)'	System	05 Oct 2020 16:47:04

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-05T11:46:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2243066b-22e4-4d3f-bece-fda41ee9c246' User entered '05 Oct 2020 11:46:58'	System	05 Oct 2020 16:47:04
	System	05 Oct 2020 16:47:04



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 71'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-12T17:35:53', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e0e04fc2-c5ac-405e-9137-aaff7f3d9aca' User entered 'No (N)'	System	12 Oct 2020 22:36:26
	System	12 Oct 2020 22:36:26

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-12T17:36:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e0e04fc2-c5ac-405e-9137-aaff7f3d9aca'	System	12 Oct 2020 22:36:26
User entered 'No (N)'	System	12 Oct 2020 22:36:26

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-12T17:36:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'e0e04fc2-c5ac-405e-9137-aaff7f3d9aca' User entered '12 Oct 2020 17:36:23'	System	12 Oct 2020 22:36:26
	System	12 Oct 2020 22:36:26

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 21:07:06



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 78'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

[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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-19T18:37:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '325b6a7e-03f6-4b4b-9e75-eec93be2f46e' User entered 'No (N)'	System	19 Oct 2020 23:38:27
	System	19 Oct 2020 23:38:27

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-19T18:38:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '325b6a7e-03f6-4b4b-9e75-eec93be2f46e'	System	19 Oct 2020 23:38:27
User entered 'No (N)'	System	19 Oct 2020 23:38:27

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-10-19T18:38:22', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '325b6a7e-03f6-4b4b-9e75-eec93be2f46e' User entered '19 Oct 2020 18:38:22'	System	19 Oct 2020 23:38:27
	System	19 Oct 2020 23:38:27

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 92'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

[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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-01T00:02:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '68da4459-18b3-4e73-b97b-551d710bc021' User entered 'No (N)'	System	01 Nov 2020 05:02:38
	System	01 Nov 2020 05:02:38



US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-01T00:02:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '68da4459-18b3-4e73-b97b-551d710bc021'	System	01 Nov 2020 05:02:38
User entered 'No (N)'	System	01 Nov 2020 05:02:38

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-01T00:02:35', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '68da4459-18b3-4e73-b97b-551d710bc021' User entered '01 Nov 2020 00:02:35'	System	01 Nov 2020 05:02:38
	System	01 Nov 2020 05:02:38

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 99'	System	04 Aug 2020 21:07:06

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

[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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-08T21:16:10', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd76c1a6b-4528-4b0a-8c97-4209f820271c' User entered 'No (N)'	System	09 Nov 2020 03:16:39
	System	09 Nov 2020 03:16:39

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-08T21:16:21', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd76c1a6b-4528-4b0a-8c97-4209f820271c' User entered 'No (N)'	System	09 Nov 2020 03:16:39
	System	09 Nov 2020 03:16:39

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-08T21:16:33', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd76c1a6b-4528-4b0a-8c97-4209f820271c' User entered '08 Nov 2020 21:16:33'	System	09 Nov 2020 03:16:39
	System	09 Nov 2020 03:16:39



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered 'Day 106'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-15T12:36:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a00cd661-ba6e-46ce-825a-e4a7311d687b' User entered 'No (N)'	System	15 Nov 2020 18:37:25
	System	15 Nov 2020 18:37:25

US3062075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:41

Have you been exposed to someone with 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)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-15T12:37:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a00cd661-ba6e-46ce-825a-e4a7311d687b' User entered 'No (N)'	System	15 Nov 2020 18:37:25
	System	15 Nov 2020 18:37:25

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-15T12:37:22', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'a00cd661-ba6e-46ce-825a-e4a7311d687b' User entered '15 Nov 2020 12:37:22'	System	15 Nov 2020 18:37:25
	System	15 Nov 2020 18:37:25

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 21:07:06

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:19
Data entry locked.	System	04 Aug 2020 21:07:06
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 21:07:06



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-23T10:49:12', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd235716b-fa1c-4600-bc42-bccb4302f664'	System	23 Nov 2020 16:49:53
User entered 'No (N)'	System	23 Nov 2020 16:49:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-23T10:49:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd235716b-fa1c-4600-bc42-bccb4302f664' User entered 'No (N)'	System	23 Nov 2020 16:49:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-23T10:49:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd235716b-fa1c-4600-bc42-bccb4302f664' User entered '23 Nov 2020 10:49:47'	System	23 Nov 2020 16:49:53
	System	23 Nov 2020 16:49:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-26T00:02:06', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2004cc44-97ab-423f-a85a-bf1ffecc82cc' User entered 'No (N)'	System	26 Nov 2020 06:02:36



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-26T00:02:15', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2004cc44-97ab-423f-a85a-bf1ffecc82cc' User entered 'No (N)'	System	26 Nov 2020 06:02:36

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-11-26T00:02:23', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2004cc44-97ab-423f-a85a-bf1ffecc82cc' User entered '26 Nov 2020 00:02:23'	System	26 Nov 2020 06:02:36
	System	26 Nov 2020 06:02:36

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-04T12:16:08', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b317216-a5e3-46f8-90dc-2d54bf97dc25'	System	04 Dec 2020 18:18:07
User entered 'No (N)'	System	04 Dec 2020 18:18:07

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-04T12:16:16', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b317216-a5e3-46f8-90dc-2d54bf97dc25'	System	04 Dec 2020 18:18:07
User entered 'No (N)'	System	04 Dec 2020 18:18:07

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-04T12:18:01', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b317216-a5e3-46f8-90dc-2d54bf97dc25' User entered '04 Dec 2020 12:18:01'	System	04 Dec 2020 18:18:07
	System	04 Dec 2020 18:18:07



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-10T09:49:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b2565c4-cf56-494d-ba12-79b68acbb1d4'	System	13 Dec 2020 02:04:01
User entered 'No (N)'	System	13 Dec 2020 02:04:01

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-10T09:37:14', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b2565c4-cf56-494d-ba12-79b68acbb1d4'	System	13 Dec 2020 02:04:01
User entered 'Yes (Y)'	System	13 Dec 2020 02:04:01

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Please 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-12T20:02:40', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b2565c4-cf56-494d-ba12-79b68acbb1d4'	System	13 Dec 2020 02:04:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 02:04:01

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-12T20:03:51', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '4b2565c4-cf56-494d-ba12-79b68acbb1d4' User entered '12 Dec 2020 20:03:51'	System	13 Dec 2020 02:04:01
	System	13 Dec 2020 02:04:01

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-17T13:37:29', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ca58903c-9cb0-421a-bb11-f89bd7fdaab1' User entered 'No (N)'	System	17 Dec 2020 19:37:48
	System	17 Dec 2020 19:37:48

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-17T13:37:36', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ca58903c-9cb0-421a-bb11-f89bd7fdaab1' User entered 'No (N)'	System	17 Dec 2020 19:37:48
	System	17 Dec 2020 19:37:48

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-17T13:37:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ca58903c-9cb0-421a-bb11-f89bd7fdaab1' User entered '17 Dec 2020 13:37:44'	System	17 Dec 2020 19:37:48

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-24T17:34:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '008c4322-5f6b-44e0-b60c-fed67ce2257e' User entered 'No (N)'	System	24 Dec 2020 23:35:40
	System	24 Dec 2020 23:35:40

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-24T17:35:05', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '008c4322-5f6b-44e0-b60c-fed67ce2257e' User entered 'No (N)'	System	24 Dec 2020 23:35:40
	System	24 Dec 2020 23:35:40

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2020-12-24T17:35:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '008c4322-5f6b-44e0-b60c-fed67ce2257e' User entered '24 Dec 2020 17:35:37'	System	24 Dec 2020 23:35:40
	System	24 Dec 2020 23:35:40

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-02T12:38:13', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '121cbd36-749a-42af-9890-579684ef3f1f' User entered 'No (N)'	System	02 Jan 2021 18:39:51
	System	02 Jan 2021 18:39:51

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-02T12:37:58', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '121cbd36-749a-42af-9890-579684ef3f1f' User entered 'No (N)'	System	02 Jan 2021 18:39:51



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-02T12:39:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '121cbd36-749a-42af-9890-579684ef3f1f' User entered '02 Jan 2021 12:39:49'	System	02 Jan 2021 18:39:51
	System	02 Jan 2021 18:39:51

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-07T17:08:31', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '910af9b3-cbef-4e04-b9e6-9e94d3247f85'	System	07 Jan 2021 23:08:47
User entered 'No (N)'	System	07 Jan 2021 23:08:47

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-07T17:08:36', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '910af9b3-cbef-4e04-b9e6-9e94d3247f85'	System	07 Jan 2021 23:08:47
User entered 'No (N)'	System	07 Jan 2021 23:08:47

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-07T17:08:45', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '910af9b3-cbef-4e04-b9e6-9e94d3247f85' User entered '07 Jan 2021 17:08:45'	System	07 Jan 2021 23:08:47
	System	07 Jan 2021 23:08:47

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-16T10:13:26', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bdbf957f-56e4-4f86-8725-305c6c7925b1' User entered 'No (N)'	System	16 Jan 2021 16:13:52

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-16T10:13:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bdbf957f-56e4-4f86-8725-305c6c7925b1'	System	16 Jan 2021 16:13:52
User entered 'No (N)'	System	16 Jan 2021 16:13:52

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-16T10:13:47', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bdbf957f-56e4-4f86-8725-305c6c7925b1' User entered '16 Jan 2021 10:13:47'	System	16 Jan 2021 16:13:52
	System	16 Jan 2021 16:13:52

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-21T10:56:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc4e01b5-90a8-40c2-bd86-305dcc193464' User entered 'No (N)'	System	21 Jan 2021 16:57:12
	System	21 Jan 2021 16:57:12

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-21T10:57:01', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc4e01b5-90a8-40c2-bd86-305dcc193464'	System	21 Jan 2021 16:57:12
User entered 'No (N)'	System	21 Jan 2021 16:57:12

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-21T10:57:09', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc4e01b5-90a8-40c2-bd86-305dcc193464' User entered '21 Jan 2021 10:57:09'	System	21 Jan 2021 16:57:12

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-28T17:59:41', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'be7e8926-134c-4e71-95b6-34fcbe7df332'	System	29 Jan 2021 00:00:00
User entered 'No (N)'	System	29 Jan 2021 00:00:00

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-28T17:59:45', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'be7e8926-134c-4e71-95b6-34fcbe7df332'	System	29 Jan 2021 00:00:00
User entered 'No (N)'	System	29 Jan 2021 00:00:00



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-01-28T17:59:56', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'be7e8926-134c-4e71-95b6-34fcbe7df332' User entered '28 Jan 2021 17:59:56'	System	29 Jan 2021 00:00:00
	System	29 Jan 2021 00:00:00

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-04T00:02:38', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ffff3000-39d0-4c1b-9b67-56e064a2bea8' User entered 'No (N)'	System	04 Feb 2021 06:02:53
	System	04 Feb 2021 06:02:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-04T00:02:44', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ffff3000-39d0-4c1b-9b67-56e064a2bea8' User entered 'No (N)'	System	04 Feb 2021 06:02:53
	System	04 Feb 2021 06:02:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-04T00:02:48', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'ffff3000-39d0-4c1b-9b67-56e064a2bea8' User entered '04 Feb 2021 00:02:48'	System	04 Feb 2021 06:02:53
	System	04 Feb 2021 06:02:53

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-11T22:32:32', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '857da788-aa9c-4666-afd9-454a68e3240f' User entered 'No (N)'	System	12 Feb 2021 04:32:49
	System	12 Feb 2021 04:32:49

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-11T22:32:37', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '857da788-aa9c-4666-afd9-454a68e3240f' User entered 'No (N)'	System	12 Feb 2021 04:32:49
	System	12 Feb 2021 04:32:49

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-11T22:32:46', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '857da788-aa9c-4666-afd9-454a68e3240f' User entered '11 Feb 2021 22:32:46'	System	12 Feb 2021 04:32:49
	System	12 Feb 2021 04:32:49

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-18T08:00:27', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8b50175e-c514-4216-b227-9c2447cbdef6' User entered 'No (N)'	System	18 Feb 2021 14:00:51
	System	18 Feb 2021 14:00:51

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-18T08:00:32', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8b50175e-c514-4216-b227-9c2447cbdef6' User entered 'No (N)'	System	18 Feb 2021 14:00:51
	System	18 Feb 2021 14:00:51

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-18T08:00:49', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '8b50175e-c514-4216-b227-9c2447cbdef6' User entered '18 Feb 2021 08:00:49'	System	18 Feb 2021 14:00:51
	System	18 Feb 2021 14:00:51

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-25T09:40:29-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '36d7e165-72e5-4169-916c-424926cdb0fe' User entered 'No (N)'	System	26 Feb 2021 02:59:00
	System	26 Feb 2021 02:59:00

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-25T09:40:36-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '36d7e165-72e5-4169-916c-424926cdb0fe' User entered 'No (N)'	System	26 Feb 2021 02:59:00
	System	26 Feb 2021 02:59:00



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-02-25T09:40:46-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '36d7e165-72e5-4169-916c-424926cdb0fe' User entered '25 Feb 2021 15:40:46'	System	26 Feb 2021 02:59:00
	System	26 Feb 2021 02:59:00

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-04T00:04:09-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'aea77a50-268f-4423-93e8-962ab66c843e' User entered 'No (N)'	System	04 Mar 2021 06:04:37
	System	04 Mar 2021 06:04:37

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-04T00:04:16-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'aea77a50-268f-4423-93e8-962ab66c843e' User entered 'No (N)'	System	04 Mar 2021 06:04:37

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-04T00:04:31-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'aea77a50-268f-4423-93e8-962ab66c843e' User entered '04 Mar 2021 00:04:31'	System	04 Mar 2021 06:04:37
	System	04 Mar 2021 06:04:37

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-11T00:32:51-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e961e62-27a3-4293-8c6e-ed8aefb5ec07'	System	11 Mar 2021 06:33:26
User entered 'No (N)'	System	11 Mar 2021 06:33:26

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-11T00:33:02-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e961e62-27a3-4293-8c6e-ed8aefb5ec07'	System	11 Mar 2021 06:33:26
User entered 'No (N)'	System	11 Mar 2021 06:33:26

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-11T00:33:23-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '3e961e62-27a3-4293-8c6e-ed8aefb5ec07' User entered '11 Mar 2021 00:33:23'	System	11 Mar 2021 06:33:26
	System	11 Mar 2021 06:33:26

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-18T01:31:41-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9cbd7b5e-9ddb-4ca7-8acc-977d4299194f' User entered 'No (N)'	System	18 Mar 2021 06:31:59
	System	18 Mar 2021 06:31:59

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-18T01:31:47-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9cbd7b5e-9ddb-4ca7-8acc-977d4299194f'	System	18 Mar 2021 06:31:59
User entered 'No (N)'	System	18 Mar 2021 06:31:59

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-18T01:31:57-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '9cbd7b5e-9ddb-4ca7-8acc-977d4299194f' User entered '18 Mar 2021 01:31:57'	System	18 Mar 2021 06:31:59
	System	18 Mar 2021 06:31:59

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-25T20:23:09-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'abf4ac98-e093-4669-89cb-759dafba3c57'	System	26 Mar 2021 01:28:35
User entered 'No (N)'	System	26 Mar 2021 01:28:35

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-25T20:23:19-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'abf4ac98-e093-4669-89cb-759dafba3c57'	System	26 Mar 2021 01:28:35
User entered 'No (N)'	System	26 Mar 2021 01:28:35



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-25T20:23:36-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'abf4ac98-e093-4669-89cb-759dafba3c57'	System	26 Mar 2021 01:28:35
User entered '25 Mar 2021 20:23:36'	System	26 Mar 2021 01:28:35

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-02T11:48:18-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '76997614-43a9-4182-ae2d-220060c6a465'	System	02 Apr 2021 16:48:38
User entered 'No (N)'	System	02 Apr 2021 16:48:38

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-02T11:48:25-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '76997614-43a9-4182-ae2d-220060c6a465'	System	02 Apr 2021 16:48:38
User entered 'No (N)'	System	02 Apr 2021 16:48:38

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-02T11:48:33-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '76997614-43a9-4182-ae2d-220060c6a465'	System	02 Apr 2021 16:48:38
User entered '02 Apr 2021 11:48:33'	System	02 Apr 2021 16:48:38

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-08T00:02:51-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc2c3ed9-493e-4b57-a874-4b90dd6d7698'	System	08 Apr 2021 05:03:24
User entered 'No (N)'	System	08 Apr 2021 05:03:24

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-08T00:02:58-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc2c3ed9-493e-4b57-a874-4b90dd6d7698'	System	08 Apr 2021 05:03:24
User entered 'No (N)'	System	08 Apr 2021 05:03:24

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-08T00:03:21-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'bc2c3ed9-493e-4b57-a874-4b90dd6d7698'	System	08 Apr 2021 05:03:24
User entered '08 Apr 2021 00:03:21'	System	08 Apr 2021 05:03:24

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:50:14



**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-15T07:22:27-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2c271182-8500-418c-8524-812dec7764d6'	System	15 Apr 2021 12:23:03
User entered 'No (N)'	System	15 Apr 2021 12:23:03

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-15T07:22:34-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2c271182-8500-418c-8524-812dec7764d6'	System	15 Apr 2021 12:23:03
User entered 'No (N)'	System	15 Apr 2021 12:23:03

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-15T07:22:46-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2c271182-8500-418c-8524-812dec7764d6'	System	15 Apr 2021 12:23:03
User entered '15 Apr 2021 07:22:46'	System	15 Apr 2021 12:23:03

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-22T00:02:41-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2205b09e-d5ec-4242-8814-83bb572eedf5' User entered 'No (N)'	System	22 Apr 2021 05:03:08
	System	22 Apr 2021 05:03:08

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-22T00:02:47-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2205b09e-d5ec-4242-8814-83bb572eedf5'	System	22 Apr 2021 05:03:08
User entered 'No (N)'	System	22 Apr 2021 05:03:08



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-22T00:03:02-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '2205b09e-d5ec-4242-8814-83bb572eedf5'	System	22 Apr 2021 05:03:08
User entered '22 Apr 2021 00:03:02'	System	22 Apr 2021 05:03:08

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-29T00:02:47-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd3d57012-f922-4734-8536-ec51d27537b6'	System	29 Apr 2021 05:03:27
User entered 'No (N)'	System	29 Apr 2021 05:03:27

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

Have you been exposed to someone with 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 (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-29T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd3d57012-f922-4734-8536-ec51d27537b6'	System	29 Apr 2021 05:03:27
User entered 'No (N)'	System	29 Apr 2021 05:03:27

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-04-29T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: 'd3d57012-f922-4734-8536-ec51d27537b6'	System	29 Apr 2021 05:03:27
User entered '29 Apr 2021 00:03:05'	System	29 Apr 2021 05:03:27

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:50:14



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:50:14



**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:50:14

**US3062075**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:57:41**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:14
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:50:14

US3062075

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:57:41**

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 22:52:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-04T00:02:58-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '242d26c7-c4ca-4be4-a399-480fd78655a2' User entered 'No (N)'	System	04 Mar 2021 06:03:42
	System	04 Mar 2021 06:03:42

**US3062075**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:52:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F0F5E4-FBF8-47A4-B09B-E516E8AC39FF)', Time: '2021-03-04T00:03:26-06:00', User OID: 'PatientReportedOutcome (US3062075)', ODM File OID: '242d26c7-c4ca-4be4-a399-480fd78655a2' User entered '04 Mar 2021 00:03:26'	System	04 Mar 2021 06:03:42
	System	04 Mar 2021 06:03:42

**US3062075**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:40
	(b) (4)	

US3062075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered '27 Oct 2020'	Justin Phillips (b) (4)	27 Oct 2020 20:15:40
	(b) (4)	

US3062075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:40
	(b) (4)	

US3062075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 20:15:40
	(b) (4)	



US3062075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:50
	(b) (4)	

**US3062075**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	27 Oct 2020 20:15:50

US3062075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Un-verified.	(b) (4)	20 Jan 2021 22:06:01
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:05:18
User entered 'Yes (Y)'	Riley King (b) (4)	27 Nov 2020 21:09:50

US3062075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:00
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:05:18
User entered '27 Nov 2020'	Riley King (b) (4)	27 Nov 2020 21:09:50

US3062075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Un-verified.	(b) (4)	20 Jan 2021 22:06:02
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:05:18
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	27 Nov 2020 21:09:50

US3062075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:06:04
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:05:18
User entered empty.	Riley King (b) (4) (b) (4)	27 Nov 2020 21:09:50

US3062075

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Un-verified.	(b) (4)	20 Jan 2021 22:05:56
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:05:25
User entered 'Yes (Y)'	Riley King (b) (4)	27 Nov 2020 21:09:54

**US3062075**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'I'	System	27 Nov 2020 21:09:54



US3062075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 19:14:58
	(b) (4)	

US3062075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:00:06
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'The data for Participant Decision Visit / OL-D1 has been updated in EDC. ' (Site from DM).	Sherry Henning (b) (4)	10 Feb 2021 22:32:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 03:56:15
User entered '29 Dec 2020'	Riley King (b) (4)	05 Jan 2021 19:14:58

US3062075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	05 Jan 2021 19:14:58
	(b) (4)	

US3062075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	05 Jan 2021 19:14:58
	(b) (4)	

US3062075

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 19:14:50

**US3062075**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'I'	System	05 Jan 2021 19:14:50

US3062075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:28:03
	(b) (4)	

US3062075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:28:03
	(b) (4)	



US3062075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	10 Feb 2021 22:28:03

US3062075

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	10 Feb 2021 22:28:03
	(b) (4)	

US3062075

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	10 Feb 2021 22:28:10

**US3062075**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'I'	System	10 Feb 2021 22:28:10

US3062075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4)	31 Mar 2021 09:47:09
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.	Janna Martinez (b) (4)	30 Mar 2021 20:39:37
' answered with 'data corrected' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:43:13
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:50:50

US3062075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'Updated per source information. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 12:58:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'Updated per source information. ' (Site from DM).	Cayla Lawless (b) (4)	10 Mar 2021 20:28:25
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:28:40
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:50:50

US3062075

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[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 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Clinic (Clinic)'	Colton King (b) (4)	25 Feb 2021 19:50:50

**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'VISIT4'	System	25 Feb 2021 19:50:50



US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Mar 2021 20:48:22
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Mar 2021 20:48:22
User entered '24 Feb 2021' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Mar 2021 20:47:11
User entered '08 Feb 2021'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '13:59' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User entered '13:05'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered '24 Feb 2021 13:59'	System	30 Mar 2021 20:48:22
User entered '08 Feb 2021 13:05'	System	30 Mar 2021 20:47:11

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	System	30 Mar 2021 20:48:22
answered by data change (Site from System).	System	30 Mar 2021 20:48:22
User entered '97.7' F reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
User entered '96.3' F	System	30 Mar 2021 20:47:11
	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '77' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User entered '68'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	



**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'bpm'	System	30 Mar 2021 20:47:11

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '12' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'breaths/min'	System	30 Mar 2021 20:47:11

US3062075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Mar 2021 20:48:22
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Mar 2021 20:48:22
User entered '99' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Mar 2021 20:47:11
User entered '13'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

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**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'mmHg'	System	30 Mar 2021 20:47:11

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Mar 2021 20:48:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	30 Mar 2021 20:48:22
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	30 Mar 2021 20:48:22
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	30 Mar 2021 20:48:22
User entered '62' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Mar 2021 20:48:22
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Mar 2021 20:47:11
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	30 Mar 2021 20:47:11
User entered '54'	Janna Martinez (b) (4)	30 Mar 2021 20:47:11
	(b) (4)	

**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'mmHg'	System	30 Mar 2021 20:47:11

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39



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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39

US3062075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:12:36
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:51:35
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4)	21 Apr 2021 12:07:55
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	20 Apr 2021 15:24:02
Signature has been broken.	(b) (4)	20 Apr 2021 15:23:49
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Apr 2021 15:23:49
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4)	20 Apr 2021 09:41:35
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:41:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Audit	User	Time (GMT)
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' answered with 'Visit 4- only symptom directed is required OL Day 29- investigator is required to assess lymph nodes and injection arm ie part of a physical.  If visit 4 did not require lab but OI D29 did, we would document as such as each tab is visit/protocol derived. ' (Site from DM).	marissa Mueller (b) (4) (b) (4)	02 Apr 2021 13:29:18
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:27:59
User closed query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:27:59
Query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' answered with 'per protocol, px not required at this visit. This would be the same if immunogenicity was drawn at one and not the other per protocol. Correct as entered' (Site from DM).	marissa Mueller (b) (4) (b) (4)	31 Mar 2021 14:55:29
User opened query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:47:22

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EAB) (1725)

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:47:22
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data correct as entered as Physical is not required for visit 4 but is required for OL-D29' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:00:11
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:43:33
User entered 'No (N)'	Colton King (b) (4)	25 Feb 2021 19:50:55

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:12:36
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:51:35
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	20 Apr 2021 15:23:49
	(b) (4)	
User entered '24 Feb 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Apr 2021 15:23:49
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Colton King (b) (4)	25 Feb 2021 19:50:55
	(b) (4)	

US3062075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Cayla Lawless (b) (4)	10 Mar 2021 20:28:14

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Cayla Lawless (b) (4)	10 Mar 2021 20:28:14

US3062075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '14:43'	Cayla Lawless (b) (4)	10 Mar 2021 20:28:14
	(b) (4)	



**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered '24 Feb 2021 14:43'	System	10 Mar 2021 20:28:14

US3062075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:51:01

**US3062075**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:39
User entered 'I'	System	25 Feb 2021 19:51:01

US3062075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	01 Apr 2021 20:40:20

US3062075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '31 Mar 2021'	Colton King (b) (4)	01 Apr 2021 20:40:20

US3062075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	01 Apr 2021 20:40:20

US3062075

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	01 Apr 2021 20:40:20

US3062075

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	01 Apr 2021 20:40:06



**US3062075**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:08
User entered 'I'	System	01 Apr 2021 20:40:06

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:10:19

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:10:19
	(b) (4)	

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	10 Feb 2021 22:10:19

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 22:10:19

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:20:39

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17



US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:20:39

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Placebo (Placebo)'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Placebo (Placebo)'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Placebo (Placebo)'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:57:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:11:17

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:57:41**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '1'	System	10 Feb 2021 22:11:17

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'I'	System	10 Feb 2021 22:11:17



US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '157.0' cm	Sherry Henning (b) (4)	10 Feb 2021 22:12:57
	(b) (4)	

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '76.1' kg	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '30.87346'	System	10 Feb 2021 22:12:57
DataPoint set to visible.	System	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '157.0' cm	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '76.1' kg	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '30.87346'	System	10 Feb 2021 22:12:57
DataPoint set to visible.	System	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '14:51'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '26 Jan 2021 14:51'	System	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '98.3' F	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '91'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'bpm'	System	10 Feb 2021 22:12:57



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'breaths/min'	System	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '110'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '73'	Sherry Henning (b) (4)	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	10 Feb 2021 22:12:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '157.0' cm	Sherry Henning (b) (4)	10 Feb 2021 22:12:57
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '76.1' kg	Sherry Henning (b) (4)	10 Feb 2021 22:12:57



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '30.87346'	System	10 Feb 2021 22:12:57
DataPoint set to visible.	System	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '17:03'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '26 Jan 2021 17:03'	System	10 Feb 2021 22:13:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 07:05:09
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	marissa Mueller (b) (4)	19 Feb 2021 23:28:45
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Feb 2021 22:13:56
User entered '96.7' F	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '78'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'bpm'	System	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '14'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'breaths/min'	System	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '107'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	10 Feb 2021 22:13:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Feb 2021 22:15:09
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	10 Feb 2021 22:15:09
User entered '71' reason for change: Data Entry Error	Sherry Henning (b) (4)	10 Feb 2021 22:15:09
	(b) (4)	
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Feb 2021 22:13:56
User entered '14'	Sherry Henning (b) (4)	10 Feb 2021 22:13:56
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	10 Feb 2021 22:13:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:18:26

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:18:26

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Sherry Henning (b) (4)	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Sherry Henning (b) (4)	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mRNA-1273'	System	10 Feb 2021 22:18:56
DataPoint set to visible.	System	10 Feb 2021 22:11:17

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:18:56



US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '16:31'	Sherry Henning (b) (4)	10 Feb 2021 22:18:56

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:57:41**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '26 Jan 2021 16:31'	System	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'ONCE'	System	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 22:18:56

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:19:25

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:19:25

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '15:03'	Sherry Henning (b) (4)	10 Feb 2021 22:19:25



US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '26 Jan 2021 15:03'	System	10 Feb 2021 22:19:25

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:19:45

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '26 Jan 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:19:45

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '14:59'	Sherry Henning (b) (4)	10 Feb 2021 22:19:45

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:57:41**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '26 Jan 2021 14:59'	System	10 Feb 2021 22:19:45

US3062075

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:19:52

**US3062075**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'I'	System	10 Feb 2021 22:19:52

**US3062075**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:57:41**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:22:02



US3062075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '04 Feb 2021'	Sherry Henning (b) (4)	10 Feb 2021 22:22:02

US3062075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	10 Feb 2021 22:22:02

US3062075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Sherry Henning (b) (4)	10 Feb 2021 22:22:02

US3062075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Feb 2021 22:22:08

**US3062075**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User entered 'I'	System	10 Feb 2021 22:22:08

**US3062075**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User entered '1'	System	10 Feb 2021 22:22:08
DataPoint set to visible.	System	10 Feb 2021 22:22:08

US3062075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:51:37

**US3062075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:51:37



US3062075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Clinic (Clinic)'	Colton King (b) (4)	25 Feb 2021 19:51:37

**US3062075**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'OLD29'	System	25 Feb 2021 19:51:37

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '13:59'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '24 Feb 2021 13:59'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '97.7' F	Colton King (b) (4)	25 Feb 2021 19:54:04



US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Oral (Oral)'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '77'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'bpm'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '12'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'breaths/min'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '99'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	25 Feb 2021 19:54:04



US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '62'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '15:34'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '24 Feb 2021 15:34'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '99.0' F	Colton King (b) (4)	25 Feb 2021 19:54:04



US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Oral (Oral)'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '72'	Colton King (b) (4)	25 Feb 2021 19:54:04

**US3062075**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'bpm'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '16'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'breaths/min'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '113'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	25 Feb 2021 19:54:04



US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '78'	Colton King (b) (4)	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	25 Feb 2021 19:54:04

US3062075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:54:14

US3062075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:54:14

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mRNA-1273'	System	25 Feb 2021 19:54:40
DataPoint set to visible.	System	10 Feb 2021 22:22:08



US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '24 Feb 2021'	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '15:02'	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '24 Feb 2021 15:02'	System	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Left Arm (LEFT ARM)'	Colton King (b) (4)	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'ONCE'	System	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 19:54:40

US3062075

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	25 Feb 2021 19:54:45

US3062075

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'I'	System	25 Feb 2021 19:54:45



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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	11 Mar 2021 19:36:05
	(b) (4)	

US3062075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '03 Mar 2021'	marissa Mueller (b) (4)	11 Mar 2021 19:36:05

US3062075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Contact Made (CONTACT MADE)'	marissa Mueller (b) (4)	11 Mar 2021 19:36:05

US3062075

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:41

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) marissa Mueller (b) (4)	11 Mar 2021 19:36:05
	(b) (4)	

US3062075

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	marissa Mueller (b) (4)	11 Mar 2021 19:36:28

**US3062075**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:57:41**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:31
User entered 'I'	System	11 Mar 2021 19:36:28

**US3062075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	26 Mar 2021 18:01:46

**US3062075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '25 Mar 2021'	Colton King (b) (4)	26 Mar 2021 18:01:46



US3062075

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:41

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Clinic (Clinic)'	Colton King (b) (4)	26 Mar 2021 18:01:46

**US3062075**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:57:41**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'OLD57'	System	26 Mar 2021 18:01:46

US3062075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '25 Mar 2021'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '14:14'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '25 Mar 2021 14:14'	System	26 Mar 2021 18:03:01

US3062075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '98.4' F	Colton King (b) (4)	26 Mar 2021 18:03:01

US3062075

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Oral (Oral)'	Colton King (b) (4)	26 Mar 2021 18:03:01



**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '81'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'bpm'	System	26 Mar 2021 18:03:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '16'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'breaths/min'	System	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '99'	Colton King (b) (4)	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '70'	Colton King (b) (4)	26 Mar 2021 18:03:01



**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered 'mmHg'	System	26 Mar 2021 18:03:01

**US3062075**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:57:41**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29

US3062075

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'No (N)'	Colton King (b) (4)	26 Mar 2021 18:03:11

US3062075

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	26 Mar 2021 18:03:11

US3062075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)'	Colton King (b) (4)	26 Mar 2021 18:03:41

US3062075

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '25 Mar 2021'	Colton King (b) (4)	26 Mar 2021 18:03:41

**US3062075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:57:41**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '14:25'	Colton King (b) (4)	26 Mar 2021 18:03:41



**US3062075**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:57:41**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:54:29
User entered '25 Mar 2021 14:25'	System	26 Mar 2021 18:03:41

US3062075

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:57:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:07:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Riley King (b) (4)	30 Dec 2020 17:51:17
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 20:00:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:33
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:51:57
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 13:51:52

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:55:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Pubis fracture - version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 18:29:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	29 Jan 2021 18:29:22
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 23:55:55
DataPoint Un-verified.	Riley King (b) (4)	28 Jan 2021 23:55:07
	(b) (4)	
Coding entries removed.	Riley King (b) (4)	28 Jan 2021 23:55:07
	(b) (4)	
User entered 'FRACTURE of superior rim right pubis' reason for change: New Information	Riley King (b) (4)	28 Jan 2021 23:55:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 19:24:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 19:24:22
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 17:56:07
User entered 'Fracture of the pelvis'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:36
User entered 'Yes (Y)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:09:22
User entered 'No (N)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:09:24
User entered 'No (N)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:12
Query 'please verify as 29Dec per hosp admit note' canceled (Site from CRA).		16 Mar 2021 17:14:10
User opened query 'please verify as 29Dec per hosp admit note' (Site from CRA).		16 Mar 2021 17:12:52
DataPoint Un-verified.		16 Mar 2021 17:12:26
DataPoint Verified.		16 Mar 2021 16:55:58
User entered '27 Dec 2020'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:00
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Dec 2020 17:57:20
User entered empty; reason for change Per Query Resolution	Riley King (b) (4)	30 Dec 2020 17:57:20
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Dec 2020 17:56:03
User entered '16:00'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 17:57:20
User entered '27 Dec 2020 16:00'	System	30 Dec 2020 17:56:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:02
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:24:25
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:09
	(b) (4), (b) (6)	16 Mar 2021 15:43:43
User closed query 'PV Query: Thank you for confirming the event remains ongoing as the fracture was not surgically fixed and will heal in 3-4 weeks. Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		
Query 'PV Query: Thank you for confirming the event remains ongoing as the fracture was not surgically fixed and will heal in 3-4 weeks. Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added' (Site from Safety).	Riley King (b) (4)	15 Mar 2021 19:24:46
	(b) (4)	
User entered '11 Mar 2021' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:24:25
	(b) (4)	
User opened query 'PV Query: Thank you for confirming the event remains ongoing as the fracture was not surgically fixed and will heal in 3-4 weeks. Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:15:22
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:15:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:12:26
User entered empty.	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:12
	(b) (4), (b) (6)	17 Feb 2021 16:19:34
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This fracture was not surgically fixed. It will heal in 3-4 weeks and remains ongoing. ' (Site from Safety).	Cayla Lawless (b) (4)	16 Feb 2021 17:21:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 20:33:03
DataPoint Verified.		20 Jan 2021 22:08:29
	(b) (4), (b) (6)	06 Jan 2021 16:22:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 17:56:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:25
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:19
User entered 'Yes (Y)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:21
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:23
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:24
	(b) (4), (b) (6)	18 Feb 2021 14:36:58
User closed query 'Per CDM: Please update the hospital discharge date once it is available else clarify.' (Site from DM).	marissa Mueller (b) (4)	17 Feb 2021 17:55:31
Query 'Per CDM: Please update the hospital discharge date once it is available else clarify.' answered with 'data is present' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Please update the hospital discharge date once it is available else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 03:50:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 03:50:05
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'still in hospital no discharge date available ' (Site from System).	Colton King (b) (4)	30 Dec 2020 19:07:22
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Dec 2020 17:56:03
User entered 'I'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:29
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm the hospital admission date as discharge summary showed a different admission date (29 Dec 2020) and update EDC accordingly.' (Site from Safety).		10 Mar 2021 17:13:50
Query 'PV Query: Please confirm the hospital admission date as discharge summary showed a different admission date (29 Dec 2020) and update EDC accordingly.' answered with 'reconciled ' (Site from Safety).	Riley King (b) (4)	09 Mar 2021 14:55:30
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	09 Mar 2021 14:55:18
	(b) (4)	
User entered '28 Dec 2020' reason for change: Data Entry Error	Riley King (b) (4)	09 Mar 2021 14:55:18
	(b) (4)	
User opened query 'PV Query: Please confirm the hospital admission date as discharge summary showed a different admission date (29 Dec 2020) and update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 19:00:38
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:08:15
User entered '27 Dec 2020'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:41
	(b) (4), (b) (6)	
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 23:18:49
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'	Riley King (b) (4)	02 Mar 2021 15:59:37
answered with 'Faxed ' (Site from Safety).	(b) (4)	
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:15:07
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 14:19:54
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'this date is present' (Site from Safety).	marissa Mueller (b) (4)	17 Feb 2021 17:54:55
	(b) (4)	
User entered '8 Jan 2021' reason for change: New Information	Riley King (b) (4)	27 Jan 2021 17:08:22
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:22:32
User entered empty.	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:44
User closed query 'Per CDM: This data is required. Please record Admitted to ICU? as Yes or No as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:32:36
Query 'Per CDM: This data is required. Please record Admitted to ICU? as Yes or No as appropriate. Otherwise clarify. Thank you.' answered with 'updated per source' (Site from DM).	marissa Mueller (b) (4)	17 Feb 2021 17:55:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 17:55:21
User opened query 'Per CDM: This data is required. Please record Admitted to ICU? as Yes or No as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:31:26
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 04:27:50
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'still in hospital discharge date unavailable' (Site from System).	Colton King (b) (4)	30 Dec 2020 19:07:48
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	30 Dec 2020 17:56:03
User entered 'Unknown (UNK)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:46
User entered empty.	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:49
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:50
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:52
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:55
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:56
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:56:58
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:15
	(b) (4), (b) (6)	25 Feb 2021 18:37:58
User closed query 'PV Query: Con meds indicate use of metaxalone for "cramping, generalized". Can the indication of "cramping, generalized" be more specific (i.e. abdominal, menstrual, muscle, etc.) Is this cramping part of medical history? If yes, please add to medical history. if new event please consider reporting as adverse event.' (Site from Safety).		
Query 'PV Query: Con meds indicate use of metaxalone for "cramping, generalized". Can the indication of "cramping, generalized" be more specific (i.e. abdominal, menstrual, muscle, etc.) Is this cramping part of medical history? If yes, please add to medical history. if new event please consider reporting as adverse event.' answered with 'Con Med has been updated' (Site from Safety).	Colton King (b) (4)	24 Feb 2021 14:29:36
	(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)	23 Feb 2021 09:06:34
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 'data present' (Site from DM).	marissa Mueller (b) (4)	17 Feb 2021 17:56:27
	(b) (4)	
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		17 Feb 2021 17:56:11
User entered '0' reason for change: Data Entry Error	marissa Mueller (b) (4)	17 Feb 2021 17:56:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User opened query 'PV Query: Con meds indicate use of metaxalone for "cramping, generalized". Can the indication of "cramping, generalized" be more specific (i.e. abdominal, menstrual, muscle, etc.) Is this cramping part of medical history? If yes, please add to medical history. if new event please consider reporting as adverse event.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 16:31:16
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	27 Jan 2021 17:08:22
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)	23 Jan 2021 06:33:02
User entered 'I'	Riley King (b) (4) (b) (4)	30 Dec 2020 17:56:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:18
User entered '1' reason for change: New Information	Riley King (b) (4)	27 Jan 2021 17:08:22
	(b) (4)	
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
DataPoint Un-verified.	Riley King (b) (4)	17 Mar 2021 20:11:06
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	17 Mar 2021 20:11:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:21
User entered '0'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:23
	(b) (4), (b) (6)	16 Mar 2021 15:43:49
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).		
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'outcome added ' (Site from Safety).	Riley King (b) (4)	15 Mar 2021 19:25:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:24:25
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:11:00
Query 'PV Query: Please provide the final event outcome, when available.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 14:26:26
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:22:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:25
User entered empty.	Riley King (b) (4)	30 Dec 2020 17:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
User closed query 'PV Query: If known, please provide date of completion of physical and occupational therapy.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:56:50
Query 'PV Query: If known, please provide date of completion of physical and occupational therapy.' answered with 'PT and OT completion date is unknown' (Site from Safety).	Colton King (b) (4)	24 Mar 2021 19:01:44
	(b) (4)	
User opened query 'PV Query: If known, please provide date of completion of physical and occupational therapy.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 14:06:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:57:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT OUT OF TOWN ON12/27/2020. SUBJECT ACCIDENTALLY FELL AND WENT TO THE HOSPITAL WHERE SHE WAS DIAGNOSED WITH FRACTURE OF THE PELVIS. SUBJECT IN FOR OL SUBJECT DECISION VISIT. PATIENT REPORTS DISCHARGE FROM HOSPITAL TOOK PLACE ON 08JAN2021 AND SUBJECT WAS TRANSPORTED TO A REHAB FACILITY ON 09JAN2021. SUBJECT UNSURE OF DATE RELEASED FROM REHAB. SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. PATIENT SIGNED RORS SITE WILL UPDATE SAE UPON RECEIPT OF NEW INFORMATION. RECEIVED MEDICAL RECORDS FROM PARIS REGIONAL MEDICAL CENTER WHERE SUBJECT WAS DIAGNOSED WITH SAE. WHILE IN THE HOSPITAL SUBJECT HAD MULTIPLE PROCEDURES DONE, CON PROCEDURE FORM UPDATED. SUBJECT ALSO GOT DIAGNOSED WITH MORE AES AE FORM UPDATED. ALSO RECEIVED MEDICATION LIST AND MAR CONMED FORM UPDATED. ALL NEW AES, PROCEDURES, AND MEDICATIONS ENTERED INTO EDC. 3/15/2021 Subject contacted site to notify and change in SAE. Subject has finished PT and OT. Subject has also stopped taking PRN pain medication for SAE. Update recorded in source and EDC. Subject's SAE considered resolved at this time.' reason for change: New Information	Riley King (b) (4) (b) (4)	15 Mar 2021 19:33:23
User closed query 'Per DM CLR: Narrative = SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. 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 20:41:33
User closed query 'Per DM CLR: Narrative = SUBJECT FELL. 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 20:41:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SUBJECT FELL. 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 does not need to be an AE. The fall is not the AE, what happened because of the fall(pelvic fracture) is the AE. ' (Site from DM).	Riley King (b) (4) (b) (4)	03 Mar 2021 19:47:26
User opened query 'Per DM CLR: Narrative = SUBJECT FELL. 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)	28 Feb 2021 02:49:48
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:38:22
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:38:06
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:38:03
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)	25 Feb 2021 18:38:02
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'accidental, updated narrative ' (Site from Safety).	Riley King (b) (4) (b) (4)	24 Feb 2021 14:36:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT OUT OF TOWN ON12/27/2020. SUBJECT accidentally FELL AND WENT TO THE HOSPITAL WHERE SHE WAS DIAGNOSED WITH FRACTURE OF THE PELVIS. SUBJECT IN FOR OL SUBJECT DECISION VISIT. PATIENT REPORTS DISCHARGE FROM HOSPITAL TOOK PLACE ON 08JAN2021 AND SUBJECT WAS TRANSPORTED TO A REHAB FACILITY ON 09JAN2021. SUBJECT UNSURE OF DATE RELEASED FROM REHAB. SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. PATIENT SIGNED RORS SITE WILL UPDATE SAE UPON RECEIPT OF NEW INFORMATION. RECEIVED MEDICAL RECORDS FROM PARIS REGIONAL MEDICAL CENTER WHERE SUBJECT WAS DIAGNOSED WITH SAE. WHILE IN THE HOSPITAL SUBJECT HAD MULTIPLE PROCEDURES DONE, CON PROCEDURE FORM UPDATED. SUBJECT ALSO GOT DIAGNOSED WITH MORE AES AE FORM UPDATED. ALSO RECEIVED MEDICATION LIST AND MAR CONMED FORM UPDATED. ALL NEW AES, PROCEDURES, AND MEDICATIONS ENTERED INTO EDC.' reason for change: New Information Query 'Per DM CLR: Narrative = SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated ' (Site from DM).	Riley King (b) (4) (b) (4)	24 Feb 2021 14:35:55
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Colton King (b) (4) (b) (4)	24 Feb 2021 14:34:42
	Colton King (b) (4) (b) (4)	24 Feb 2021 14:32:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'updated' (Site from Safety).	Colton King (b) (4) (b) (4)	24 Feb 2021 14:32:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Colton King (b) (4) (b) (4)	24 Feb 2021 14:32:05
User closed query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 14:26:37
Query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' answered with 'fall is event that caused SAE, not an event in itself.' (Site from Safety).	marissa Mueller (b) (4) (b) (4)	17 Feb 2021 17:57:34
User opened query 'Per DM CLR: Narrative = SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. 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 01:56:14



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT OUT OF TOWN ON12/27/2020. SUBJECT FELL AND WENT TO THE HOSPITAL WHERE SHE WAS DIAGNOSED WITH FRACTURE OF THE PELVIS. SUBJECT IN FOR OL SUBJECT DECISION VISIT. PATIENT REPORTS DISCHARGE FROM HOSPITAL TOOK PLACE ON 08JAN2021 AND SUBJECT WAS TRANSPORTED TO A REHAB FACILITY ON 09JAN2021. SUBJECT UNSURE OF DATE RELEASED FROM REHAB. SUBJECT BEGAN OT AND PT TWICE WEEKLY UPON RETURNING HOME. PATIENT SIGNED RORS SITE WILL UPDATE SAE UPON RECEIPT OF NEW INFORMATION. Received medical records from Paris regional medical center where subject was diagnosed with SAE. While in the hospital subject had multiple procedures done, Con procedure form updated. Subject also got diagnosed with more AEs AE form updated. Also received medication list and MAR ConMed form updated. All new AEs, procedures, and medications entered into EDC.' reason for change: New Information	Riley King (b) (4) (b) (4)	03 Feb 2021 14:46:30
User entered 'SUBJECT OUT OF TOWN ON12/27/2020. SUBJECT FELL AND WENT TO THE HOSPITAL WHERE SHE WAS DIAGNOSED WITH FRACTURE OF THE PELVIS. Subject in for OL subject decision visit. Patient reports discharge from hospital took place on 08JAN2021 and subject was transported to a rehab facility on 09JAN2021. Subject unsure of date released from rehab. Subject began OT and PT twice weekly upon returning home. Patient signed RORs site will update SAE upon receipt of new information.' reason for change: New Information	Riley King (b) (4) (b) (4)	27 Jan 2021 17:08:22
User opened query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:23:15
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:23:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:22:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:22:49
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)	06 Jan 2021 16:22:40
User entered 'Subject out of town on 12/27/2020. Subject fell and went to the hospital where she was diagnosed with fracture of the pelvis.'	Riley King (b) (4) (b) (4)	30 Dec 2020 17:56:03

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 17:56:03

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 17:56:03

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 17:56:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:43
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:00:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:00:23
Data point term sent to Coder	System	28 Jan 2021 23:59:58
User entered 'Bilateral lower extremity edema'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '15 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:53
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:58:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:55
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:57
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:59
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:58:58



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:16:01
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:58:58
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 23:58:58

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Jan 2021 23:58:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:01:23
	(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 00:01:23
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 00:00:59
User entered 'Acute respiratory failure'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '31 Dec 2020' reason for change: New Information	Cayla Lawless (b) (4)	16 Feb 2021 16:06:21
	(b) (4)	
User entered '4 Jan 2021' reason for change: New Information	Riley King (b) (4)	03 Feb 2021 13:24:29
	(b) (4)	
User entered '9 Jan 2021'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 00:00:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 00:00:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
	(b) (4), (b) (6)	
User closed query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance ' (Site from DM).		19 Feb 2021 13:19:37
Query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance ' answered with 'Does not meet criteria. Did prolong hospitalization and was not initial reason for hospitalization. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 17:19:25
	(b) (4)	
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 15:43:58
User entered 'No (N)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	



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Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User closed query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #25 and 26 recorded that matches this AE. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:20:34
Query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #25 and 26 recorded that matches this AE. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'Updated per source. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 17:20:03
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 17:19:54
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #25 and 26 recorded that matches this AE. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 01:57:14
User entered '1'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '1' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 17:19:54
	(b) (4)	
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 00:00:03



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Jan 2021 00:00:03

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Fractured sacrum, LLT: Fractured sacrum - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 18:30:21
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 18:30:21
Data point term sent to Coder	System	29 Jan 2021 00:01:01
User entered 'Fracture of the sacrum'	Riley King (b) (4)	29 Jan 2021 00:00:51
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Jan 2021 00:03:12
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	29 Jan 2021 00:03:12
User entered '27 Dec 2020' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	29 Jan 2021 00:03:12
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	29 Jan 2021 00:00:51
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	29 Jan 2021 00:00:51
User entered '27 Jan 2020'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User entered empty.	System	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)' reason for change: New Information	Riley King (b) (4) (b) (4)	15 Mar 2021 19:22:50
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '11 Mar 2021' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:22:50
User entered empty.	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 00:00:51
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User entered empty.	System	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51



US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	29 Jan 2021 00:00:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

US3062075

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Riley King (b) (4)	15 Mar 2021 19:22:50
New Information	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	29 Jan 2021 00:00:51
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

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 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:00:51

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:00:51

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User entered '0'	System	29 Jan 2021 00:00:51

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37
User entered '1'	System	29 Jan 2021 00:00:51

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:37

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:02:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:02:23
Data point term sent to Coder	System	29 Jan 2021 00:02:11
User entered 'Hypoxia'	Riley King (b) (4)	29 Jan 2021 00:01:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '2 Jan 2021' reason for change: New Information	Cayla Lawless (b) (4)	16 Feb 2021 16:13:45
User entered '9 Jan 2021'	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 00:01:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User entered empty.	System	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:41:21
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 17:28:26
DataPoint Un-verified.	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 17:28:11
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	23 Mar 2021 17:28:11
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:50:29
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	23 Mar 2021 17:28:11
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	23 Mar 2021 17:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User entered empty.	System	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Riley King (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

US3062075

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User closed query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #38 and 39 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:57:00
Query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #38 and 39 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'reconciled' (Site from DM).	Riley King (b) (4) (b) (4)	03 Mar 2021 19:35:49
User entered '0' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	03 Mar 2021 19:35:29
User opened query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #38 and 39 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 02:49:59
User entered '1'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '1' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	03 Mar 2021 19:35:29
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	23 Mar 2021 17:28:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	23 Mar 2021 17:28:11
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

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 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:01:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:01:39

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User entered '0'	System	29 Jan 2021 00:01:39

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39
User entered '1'	System	29 Jan 2021 00:01:39



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:39

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:57:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 00:02:23
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 00:02:11
User entered 'Generalized pain'	Riley King (b) (4)	29 Jan 2021 00:02:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '28 Dec 2020' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 16:02:25
User entered '9 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User entered empty.	System	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)' reason for change: New Information	Riley King (b) (4) (b) (4)	15 Mar 2021 19:22:08
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '11 Mar 2021' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:22:08
User entered empty.	(b) (4)	
	Riley King (b) (4)	29 Jan 2021 00:02:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User entered empty.	System	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07



US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07



US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:46:29
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		16 Feb 2021 15:51:31
User entered '0' reason for change: Data Entry Error Cayla Lawless	(b) (4)	16 Feb 2021 15:51:31
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	16 Feb 2021 15:51:21
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'Information updated per source .' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 15:51:08
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #12 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 01:57:27
User entered '1'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '1' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 15:51:21
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

US3062075

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 00:02:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 00:02:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Riley King (b) (4)	29 Jan 2021 00:02:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 00:02:07
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:02:07
	(b) (4)	



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Form: Adverse Events (9)

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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 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:07

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	29 Jan 2021 00:02:07
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User entered '0'	System	29 Jan 2021 00:02:07

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59
User entered '1'	System	29 Jan 2021 00:02:07

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:57:59

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:38
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Pubis fracture - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 15:48:27
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 15:48:27
Data point term sent to Coder	System	03 Feb 2021 13:24:46
User entered 'Right inferior pubis fracture'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.		16 Mar 2021 18:09:41
DataPoint Verified.		16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	(b) (4) Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.		16 Mar 2021 18:09:43
DataPoint Verified.		16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	(b) (4) Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:35:57
User closed query 'please verify onset of fracture is same date as entry #1 per source' (Site from CRA).		17 Mar 2021 14:35:55
Query 'please verify onset of fracture is same date as entry #1 per source' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 21:43:53
	(b) (4)	
User entered '27 Dec 2020' reason for change: Per Query Resolution	Riley King (b) (4)	16 Mar 2021 21:43:45
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:17:01
DataPoint Verified.		16 Mar 2021 18:15:16
DataPoint Un-verified.		16 Mar 2021 18:09:32
DataPoint Verified.		16 Mar 2021 18:09:20
User opened query 'please verify onset of fracture is same date as entry #1 per source' (Site from CRA).		16 Mar 2021 17:18:05
User entered '29 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:23:51
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:46
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User entered empty.	System	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.		16 Mar 2021 18:09:47
DataPoint Verified.		16 Mar 2021 18:09:20
User entered 'No (N)' reason for change: New Information	Riley King (b) (4) (b) (4)	15 Mar 2021 19:23:29
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '11 Mar 2021' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:23:29
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:50
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User entered empty.	System	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:52
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:56
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

US3062075

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:58
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:59
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:04
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:07
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:11
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:13
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:15
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:16
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:18
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:20
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41



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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:22
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:28
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:24
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Riley King (b) (4) (b) (4)	15 Mar 2021 19:23:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4) (b) (4)	29 Jan 2021 00:02:41

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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 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:10:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User entered '0'	System	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
User entered '1'	System	03 Feb 2021 13:23:51
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:25
DataPoint activated with code reason code Data required.	Riley King (b) (4)	03 Feb 2021 13:21:31
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	29 Jan 2021 00:02:41

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
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: Kyphosis, LLT: Kyphosis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:41:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:41:44
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:40:52
User entered 'Kyphosis'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:39:53



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:39:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (11)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (11)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:39:53
	(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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	



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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:39:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:39:53

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:39:53

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 22:40:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 22:40:49
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:40:52
User entered 'Multilevel spondylosis'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	



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Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:40:38

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:40:38

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	



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Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:40:38
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:40:38

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 13:40:38

US3062075

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Spleen disorders, PT: Splenic calcification, LLT: Splenic calcification - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:12:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:12:58
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:41:53
User entered 'Calcification of the spleen'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:41:16

US3062075

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:41:16



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	



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Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:41:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:41:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:41:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12



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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 13:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 13:43:44
Data point term sent to Coder	System	03 Feb 2021 13:42:54
User entered 'Generalized nausea'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

US3062075

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '28 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:42:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User entered empty.	System	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16



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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:42:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User entered empty.	System	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16



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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

US3062075

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

US3062075

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

US3062075

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:42:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (14)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:42:16
	(b) (4)	



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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:57:41

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 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:42:16



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**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User entered '0'	System	03 Feb 2021 13:42:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12
User entered '1'	System	03 Feb 2021 13:42:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:00:12

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:44:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:44:44
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:43:54
User entered 'Mitral regurgitation'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:43:10

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:43:10

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	



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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	



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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Form: Adverse Events (15)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (15)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

US3062075

Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:10
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:43:10

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:43:10

US3062075

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Tricuspid valvular disorders, PT: Tricuspid valve incompetence, LLT: Tricuspid regurgitation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:44:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 13:44:44
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:43:54
User entered 'Tricuspid regurgitation'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	



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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:43:54

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:43:54



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Folder: Adverse Events

Form: Adverse Events (16)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (16)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	



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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:43:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:43:54

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:43:54

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: Left ventricular hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:18:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:18:47
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:44:56
User entered 'Concentric left ventricular hypertrophy'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	



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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:44:40

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	



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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:44:40

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (17)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	



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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (17)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:44:40
	(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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:44:40
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:44:40



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:44:40

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Folder: Adverse Events

Form: Adverse Events (18)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Atrial enlargement, LLT: Atrial enlargement - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 14:08:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 14:08:37
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:45:57
User entered 'Dilated atrium'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:45:10



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:45:10

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	



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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	



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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:45:10
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:45:10

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:45:10

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Cardiomegaly, LLT: Cardiomegaly - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:13:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:13:51
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:46:57
User entered 'Cardiomegaly without acute abnormality'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '2 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:46:16

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:46:16

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:46:16
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:46:16

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:46:16

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Respiratory and pulmonary investigations (excl blood gases), HLT: Respiratory and pulmonary function diagnostic procedures, PT: Total lung capacity decreased, LLT: Total lung capacity decreased - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:34:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:34:48
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 13:24:55
User closed query 'CDM Coding, please split the term 'LOW LUNG VOLUME WITH BIBASILAR ATELECTASIS' into separate records, as 'LOW LUNG VOLUME'(Clarify Inspiratory capacity decreased/ Expiratory reserve volume decreased etc) and 'BIBASILAR ATELECTASIS'' reporting each term separately with all relevant information e.g. start and stop dates etc' (Site from System).	System	08 Apr 2021 13:24:53
Query 'CDM Coding, please split the term 'LOW LUNG VOLUME WITH BIBASILAR ATELECTASIS' into separate records, as 'LOW LUNG VOLUME'(Clarify Inspiratory capacity decreased/ Expiratory reserve volume decreased etc) and 'BIBASILAR ATELECTASIS'' reporting each term separately with all relevant information e.g. start and stop dates etc' answered with 'separated' (Site from System).	marissa Mueller (b) (4)	08 Apr 2021 13:24:53
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 13:23:53
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 13:23:51
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 13:23:51
	(b) (4)	
User entered 'LOW LUNG VOLUME' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 13:23:51
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding, please split the term 'LOW LUNG VOLUME WITH BIBASILAR ATELECTASIS' into separate records, as 'LOW LUNG VOLUME'(Clarify Inspiratory capacity decreased/ Expiratory reserve volume decreased etc) and 'BIBASILAR ATELECTASIS'' reporting each term separately with all relevant information e.g. start and stop dates etc' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:24:33
	Richard Glover (b) (4)	31 Mar 2021 20:55:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:09:20
Data point term sent to Coder	System	03 Feb 2021 13:47:59
User entered 'Low lung volume with bibasilar atelectasis'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:47:01

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '2 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:47:01

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:47:01

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:01
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:47:01

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (20)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:47:01



US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Non-site specific vascular disorders NEC, PT: Vascular calcification, LLT: Vascular calcification - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 12:13:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 12:13:46
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:47:59
User entered 'Atherosclerotic vascular calcification'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:47:49

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:47:49

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		10 Feb 2021 21:47:54
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	03 Feb 2021 13:47:49
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0' reason for change: Data Entry Error	Sherry Henning (b) (4)	10 Feb 2021 21:47:54
	(b) (4)	
User entered '1'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:47:49
	(b) (4)	



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:47:49

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (21)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:47:49

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Arterial calcification - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 13:46:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 13:46:44
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:49:00
User entered 'Calcification at origins of the mesenteric and renal arteries.'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:48:45

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:48:45

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (22)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Form: Adverse Events (22)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Form: Adverse Events (22)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	



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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	



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Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:48:45
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:48:45

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (22)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:48:45

US3062075

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Basilar atelectasis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:25:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:25:47
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:50:01
User entered 'Bibasilar dependent atelectasis'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:49:43

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Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:49:43

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (23)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (23)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:49:43
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:49:43

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:49:43

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiac steatosis, LLT: Fatty infiltration of heart - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:29:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:29:52
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:51:01
User entered 'Fatty infiltration of right ventricular wall'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	



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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:50:24

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Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:50:24

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Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	



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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:50:24
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:50:24

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (24)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:50:24



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
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: Scoliosis, LLT: Thoracogenic scoliosis - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 17:12:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 17:12:58
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 13:52:02
User entered 'Thoracic dextroscoliosis'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:51:47

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 13:51:47

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'I'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered '0'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:09:20
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:51:47
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 13:51:47

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 13:51:47

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 20:17:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 20:17:49
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 20:17:17
User entered 'worsening depression'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Yes (Y)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'No (N)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'No (N)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '12 Jan 2021'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	



**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 20:17:02

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
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)	01 Apr 2021 08:40:34
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE still ongoing ' (Site from DM).	Colton King (b) (4)	31 Mar 2021 20:42:54
	(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. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:18:28
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Yes (Y)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 20:17:02

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'No (N)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered 'I'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered '0'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:54
DataPoint Verified.		18 Mar 2021 00:28:46
DataPoint Un-verified.		18 Mar 2021 00:28:39
DataPoint Verified.		18 Mar 2021 00:28:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

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 20:55:19
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:56
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:28:33
User entered empty.	Riley King (b) (4)	17 Mar 2021 20:17:02
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 20:17:02

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (28)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 20:17:02

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Atelectasis, LLT: Basilar atelectasis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 15:24:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 15:24:53
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 13:28:01
User entered 'bibasilar atelectasis'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '02 Jan 2021'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 09 Jun 2021 14:57:41**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 13:27:23

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 09 Jun 2021 14:57:41**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 13:27:23

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '1'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	



US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

US3062075

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 14:57:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:01
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	08 Apr 2021 13:27:23
	(b) (4)	

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 09 Jun 2021 14:57:41**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 13:27:23

**US3062075**

**Folder: Adverse Events**

**Form: Adverse Events (29)**

**Generated On: 09 Jun 2021 14:57:41**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 13:27:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:57:41

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:09:53
User closed query 'Per CDM: re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever (05 Sep). There was a response that the concomitant medication will be updated, however there is still no matching medication even though there was a recent safety call. Please update the ConMed eCRF, or clarify. Thank you! ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:29:21
Query 'Per CDM: re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever (05 Sep). There was a response that the concomitant medication will be updated, however there is still no matching medication even though there was a recent safety call. Please update the ConMed eCRF, or clarify. Thank you! ' answered with 'Subject reported that medication recorded inadvertently in diary. No medication taken ' (Site from DM).	Jeri King (b) (4)	21 Sep 2020 19:36:09
User opened query 'Per CDM: re-query of a system query on Diary Dose 2 (1), Temperature day, Day 5. Per the participant response, medication was taken to treat pain or fever (05 Sep). There was a response that the concomitant medication will be updated, however there is still no matching medication even though there was a recent safety call. Please update the ConMed eCRF, or clarify. Thank you! ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:03:59
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:06:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 23:11:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 23:11:19
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 23:10:54
User entered 'atorvastatin'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'hyperlipidemia'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '40'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4), (b) (6)	
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).		13 Aug 2020 19:09:14
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.'	Sherry Henning (b) (4)	11 Aug 2020 23:20:44
answered with 'correct as entered' (Site from System).	(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	11 Aug 2020 23:20:27
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Aug 2020 23:20:27
User entered '01 Jan 2005' reason for change: Data Entry Error	Sherry Henning (b) (4)	11 Aug 2020 23:20:27
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Aug 2020 23:10:39
User entered '01 Jan 2200'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	11 Aug 2020 23:10:39
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:10:39

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:10:39



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:10:39

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 15:56:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 15:56:58
Data point term sent to Coder	System	16 Feb 2021 15:56:18
Coding entries removed.	Cayla Lawless (b) (4)	16 Feb 2021 15:56:04
User entered 'LEVOTHYROXINE' reason for change: Data Entry Error	(b) (4)	16 Feb 2021 15:56:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:48:17
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:48:17
Data point term sent to Coder	System	11 Aug 2020 23:11:54
User entered 'lecothyroxine'	Sherry Henning (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'hypothyroidism'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '88'	Sherry Henning (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'ug (ug)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Sherry Henning (b) (4)	11 Aug 2020 23:11:48



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	13 Aug 2020 19:09:34
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 'correct as entered' (Site from System).	Sherry Henning (b) (4)	11 Aug 2020 23:21:00
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	11 Aug 2020 23:11:48
User entered '01 Jan 1990'	Sherry Henning (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 15:56:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '09 Jan 2021' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 15:56:04
User entered empty.	(b) (4) Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:11:48



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User entered '1'	System	11 Aug 2020 23:11:48

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User entered '1'	System	11 Aug 2020 23:11:48

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:51
User entered '804 (804)'	System	11 Aug 2020 23:11:48

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 01:24:26
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 01:24:26
Data point term sent to Coder	System	11 Aug 2020 23:13:58
User entered 'metoprolol'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'cardiac palpitation'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '100'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'twice daily (BID)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	13 Aug 2020 19:09:49
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 'correct as entered' (Site from System).	Sherry Henning (b) (4)	11 Aug 2020 23:21:08
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).	(b) (4)	
User entered '01 Jan 2005'	System	11 Aug 2020 23:13:33
	Sherry Henning (b) (4)	11 Aug 2020 23:13:33
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:47:33
Query 'please verify as 11Jan21 per CM log' canceled (Site from CRA).		17 Mar 2021 17:47:29
User opened query 'please verify as 11Jan21 per CM log' (Site from CRA).		17 Mar 2021 17:47:24
User closed query 'please verify as 11Jan21 per CM log' (Site from CRA).		17 Mar 2021 17:47:24
Query 'please verify as 11Jan21 per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	17 Mar 2021 15:27:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), marissa Mueller (b) (4)	17 Mar 2021 15:27:04
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:12
DataPoint Verified.		16 Mar 2021 18:12:02
User opened query 'please verify as 11Jan21 per CM log' (Site from CRA).		16 Mar 2021 17:28:36
User entered 'Yes (Y)'	Sherry Henning (b) (4)	11 Aug 2020 23:13:33



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:47:35
User entered '11 Jan 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	17 Mar 2021 15:27:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:14
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	11 Aug 2020 23:13:33

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User entered '2'	System	11 Aug 2020 23:13:33

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User entered '1'	System	11 Aug 2020 23:13:33

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:59
User entered '804 (804)'	System	11 Aug 2020 23:13:33

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:37:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:37:55
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 23:36:24
User entered 'Famotidine'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4), (b) (6)	
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)	29 Sep 2020 08:09:32
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 'medical history corrected' (Site from DM).	Jeri King (b) (4)	28 Sep 2020 18:55:33
	(b) (4), (b) (6)	
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)	28 Sep 2020 06:19:08
User entered 'gastroesophageal reflux disease'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '40'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:57:41**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '01 Jul 2020'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	08 Sep 2020 23:36:02
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 23:36:02

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 23:36:02

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 23:36:02

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event 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)	12 Oct 2020 09:38:14
Query 'Per DM CLR: Con Med was added during the Sherry Henning study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Medication change is due to natural progression of disease.' (Site from DM).	(b) (4)	10 Oct 2020 17:18:17
User opened query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event 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)	09 Oct 2020 06:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Sep 2020 12:07:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Sep 2020 12:07:40
Data point term sent to Coder	System	10 Sep 2020 20:10:35

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'paroxetine'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:09:46
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'medical history updated' (Site from DM).	Jeri King (b) (4)	28 Sep 2020 19:00:52
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:19:49
User entered 'depression'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '25'	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '17 Aug 2020'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:52:27
User closed query 'please verify as 11Jan21 per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:52:21
Query 'please verify as 11Jan21 per CM log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	17 Mar 2021 15:28:18
DataPoint Un-verified.	marissa Mueller (b) (4)	17 Mar 2021 15:28:14
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	17 Mar 2021 15:28:14
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User opened query 'please verify as 11Jan21 per CM log' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:29:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	17 Mar 2021 17:52:24
DataPoint Un-verified.	marissa Mueller (b) (4)	17 Mar 2021 15:28:14
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 15:28:14
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	10 Sep 2020 20:09:36

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User entered '1'	System	10 Sep 2020 20:09:36



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User entered '1'	System	10 Sep 2020 20:09:36

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:09
User entered '804 (804)'	System	10 Sep 2020 20:09:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 17:30:02
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)	27 Oct 2020 20:16:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 20:16:30
Data point term sent to Coder	System	27 Oct 2020 20:15:40
User entered 'Influenza Vaccine'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Influenza prophylaxis'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0.5'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mL (mL)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '13 Oct 2020'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'No (N)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '13 Oct 2020'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Justin Phillips (b) (4)	27 Oct 2020 20:15:19
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User entered empty.	System	27 Oct 2020 20:15:19

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User entered empty.	System	27 Oct 2020 20:15:19

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:17
User entered empty.	System	27 Oct 2020 20:15:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:28:23
Data point term sent to Coder	System	28 Jan 2021 23:27:26
User entered 'Gabapentin'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	17 Feb 2021 12:45:49
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 'This item initially not entered into ecrf. Updated per source. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 15:21:53
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)	12 Feb 2021 07:49:19
User entered 'Chronic back pain'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '300'	Riley King (b) (4)	28 Jan 2021 23:26:26



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2019' reason for change: Data Entry Error	Sherry Henning (b) (4)	04 Mar 2021 14:59:45
User entered '30 Jan 2019'	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:26:26



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:26:26

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User entered '1'	System	28 Jan 2021 23:26:26

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User entered '1'	System	28 Jan 2021 23:26:26

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:25
User entered '804 (804)'	System	28 Jan 2021 23:26:26

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	28 Jan 2021 23:28:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:28:23
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 23:27:26
User entered 'Miralax'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Constipation, recurrent'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '17'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'g (g)'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '21 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 23:27:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 23:27:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	28 Jan 2021 23:27:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 23:27:11
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:27:11
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:27:11

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:27:11

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:27:11



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 20:19:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:19:50
Data point term sent to Coder	System	17 Mar 2021 20:19:18
Coding entries removed.	Riley King (b) (4)	17 Mar 2021 20:18:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:38:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:38:23
Data point term sent to Coder	System	28 Jan 2021 23:37:31
User entered 'Mirtazapine'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:28:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	17 Mar 2021 20:18:55
	(b) (4)	
User entered 'worsening DEPRESSION' reason for change: Data Entry Error	Riley King (b) (4)	17 Mar 2021 20:18:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Depression'	Riley King (b) (4)	28 Jan 2021 23:37:19
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '30'	Riley King (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '12 Jan 2021'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)' reason for change: New Information	Sherry Henning (b) (4)	04 Mar 2021 15:01:27
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '10 Feb 2021' reason for change: New Information	Sherry Henning (b) (4)	04 Mar 2021 15:01:27
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:37:19

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User entered '1'	System	28 Jan 2021 23:37:19



US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User entered '1'	System	28 Jan 2021 23:37:19

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:09:34
User entered '804 (804)'	System	28 Jan 2021 23:37:19

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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: RANITIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANTAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:39:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:39:24
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 23:38:35
User entered 'Zantac'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'GERD'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '75'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	Stephan Penn (b) (4)	16 Mar 2021 18:12:02
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '12 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:37:51
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:37:51

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:37:51

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:37:51

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
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)	28 Jan 2021 23:39:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:39:23
Data point term sent to Coder	System	28 Jan 2021 23:38:35
User entered 'Tylenol'	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: This Conmed is given for the AE#9. 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.	(b) (4), (b) (6)	17 Feb 2021 12:46:10
' (Site from DM).		
Query 'Per DM CLR: This Conmed is given for the AE#9. 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.	Cayla Lawless (b) (4)	16 Feb 2021 15:53:18
' answered with 'updated per source. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: This Conmed is given for the AE#9. 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.	(b) (4), (b) (6)	12 Feb 2021 07:49:33
' (Site from DM).		
User entered 'Generalized pain'	Riley King (b) (4)	28 Jan 2021 23:38:30
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '500'	Riley King (b) (4)	28 Jan 2021 23:38:30



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:38:30



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '16 Jan 2021'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:38:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User entered empty.	System	28 Jan 2021 23:38:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User entered empty.	System	28 Jan 2021 23:38:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:05
User entered empty.	System	28 Jan 2021 23:38:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 09:42:15
	(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 Jan 2021 09:42:15
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 23:39:35
User entered 'Bisacodyl'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Constipation, recurrent'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '10'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Rectal (RECTAL)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '18 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:39:23
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:39:23

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:39:23

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 23:39:23



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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 22:39:24
	(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 Jan 2021 22:39:24
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 23:40:36
User entered 'Colace'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Constipation, recurrent'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '100'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'twice daily (BID)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '18 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:40:00
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Jan 2021 23:40:00



US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 23:40:00

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jan 2021 23:40:00

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:41:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 23:41:23
Data point term sent to Coder	System	28 Jan 2021 23:40:36
User entered 'Cymbalta'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Depression'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '60'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:40:35



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '21 Jan 2019'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:40:35



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:40:35

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User entered '1'	System	28 Jan 2021 23:40:35

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User entered '1'	System	28 Jan 2021 23:40:35

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:20
User entered '804 (804)'	System	28 Jan 2021 23:40:35

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPOTHYROIDISM worsened. If yes, please review if an AE of worsening HYPOTHYROIDISM should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 02:09:13
Query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPOTHYROIDISM worsened. If yes, please review if an AE of worsening HYPOTHYROIDISM should be recorded. Update all applicable eCRFs if appropriate.' answered with 'Increase due to natural disease progression. ' (Site from DM).	Cayla Lawless (b) (4)	10 Mar 2021 20:30:15
	(b) (4)	
User opened query 'Per DM CLR: Please review if the dose of this med was increased because the patient's medical history of HYPOTHYROIDISM worsened. If yes, please review if an AE of worsening HYPOTHYROIDISM should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 11:16:26
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #2 (88 mcg, 01JAN1990- ongoing). Please review dates to resolve overlap as appropriate or provide comment. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:04:29
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #2 (88 mcg, 01JAN1990- ongoing). Please review dates to resolve overlap as appropriate or provide comment. ' answered with 'Stop date for other dose of Levothyroxine updated per source. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 15:57:10
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #2 (88 mcg, 01JAN1990- ongoing). Please review dates to resolve overlap as appropriate or provide comment. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:50:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:42:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:42:23
Data point term sent to Coder	System	28 Jan 2021 23:41:37
User entered 'Levothyroxine'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:41:21

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Hypothyroidism'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '112'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'ug (ug)' reason for change: New Information	Janna Martinez (b) (4)	01 Mar 2021 18:18:30
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:07:56
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated per new information. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 15:58:18
	(b) (4)	
User entered 'Other (OTHER)' reason for change: New Information	Cayla Lawless (b) (4)	16 Feb 2021 15:58:01
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:49:48
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4), (b) (6)	
User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).		02 Mar 2021 05:34:13
Query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' answered with 'data corrected' (Site from DM).	Janna Martinez (b) (4)	01 Mar 2021 18:18:41
	(b) (4)	
User entered empty; reason for change Data Entry Error	Janna Martinez (b) (4)	01 Mar 2021 18:18:30
	(b) (4)	
User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options from the drop-down list provided for Dose unit. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:30:27
User entered 'mcg' reason for change: Data Entry Error	Cayla Lawless (b) (4)	16 Feb 2021 15:58:01
	(b) (4)	
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '10 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:41:21
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 23:41:21

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 23:41:21

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jan 2021 23:41:21

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: LIDODERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 10:07:24
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 10:07:24
Data point term sent to Coder	System	28 Jan 2021 23:47:48
Data point term sent to Coder	System	28 Jan 2021 23:45:47
User entered 'Lidoderm 5%'	Riley King (b) (4)	28 Jan 2021 23:44:53



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	17 Feb 2021 13:04:44
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 'MH eCRF updated to include chronic back pain. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 15:59:09
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)	12 Feb 2021 07:50:44
User entered 'Chronic back pain'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Patch'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Riley King (b) (4)	28 Jan 2021 23:47:00
User entered 'Other (OTHER)'	Riley King (b) (4)	28 Jan 2021 23:44:53



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty; reason for change Data Entry Error	Riley King (b) (4)	28 Jan 2021 23:47:00
User entered 'Topical'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '13 Jan 2019'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:44:53

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User entered '1'	System	28 Jan 2021 23:44:53

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User entered '1'	System	28 Jan 2021 23:44:53



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:45
User entered '804 (804)'	System	28 Jan 2021 23:44:53

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES, PRODUCT: METAXALONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:57:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:57:50
Data point term sent to Coder	System	24 Feb 2021 14:28:54
Coding entries removed.	Colton King (b) (4) (b) (4)	24 Feb 2021 14:28:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES, PRODUCT: METAXALONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 09:59:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 09:59:15
Data point term sent to Coder	System	28 Jan 2021 23:46:47
User entered 'Metaxalone'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Generalized Muscle CRAMPING'	Colton King (b) (4)	24 Feb 2021 14:28:32
reason for change: Data Entry Error	(b) (4)	
User entered 'Cramping, generalized'	Riley King (b) (4)	28 Jan 2021 23:45:59
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '400'	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'three times daily (TID)'	Riley King (b) (4)	28 Jan 2021 23:45:59



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Jan 2019'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:45:59



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User entered '3'	System	28 Jan 2021 23:45:59

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User entered '1'	System	28 Jan 2021 23:45:59

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:12
User entered '804 (804)'	System	28 Jan 2021 23:45:59

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:50:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 23:50:23
Data point term sent to Coder	System	28 Jan 2021 23:49:49
User entered 'Metoprolol'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:49:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Hypertension'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '100'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '12 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:49:11
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 23:49:11

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 23:49:11

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jan 2021 23:49:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CARBONATE/VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:38:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:38:24
Data point term sent to Coder	System	28 Jan 2021 23:54:54
User entered 'Calcium carbonate vitamin D3 600 mg'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Fracture of superior rim right pubis'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'tablet (TABLET)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'three times daily (TID)'	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '29 Dec 2020' reason for change: Data Entry Error	Sherry Henning (b) (4)	03 Mar 2021 16:41:58
User entered '10 Jan 2021'	Riley King (b) (4)	28 Jan 2021 23:53:58



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:28:21
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)	06 Apr 2021 04:22:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
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 'updated' (Site from DM).	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:45:27
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:44:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:44:56
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) (4), (b) (6)	29 Mar 2021 11:19:06
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:28:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	02 Apr 2021 19:44:56
	(b) (4)	
User entered '11 Mar 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	02 Apr 2021 19:44:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	28 Jan 2021 23:53:58
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	28 Jan 2021 23:53:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User entered '3'	System	28 Jan 2021 23:53:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User entered '1'	System	28 Jan 2021 23:53:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:24
User entered '804 (804)'	System	28 Jan 2021 23:53:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:54:44
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 14:54:44
Data point term sent to Coder	System	03 Feb 2021 14:00:08
User entered 'Morphine'	Riley King (b) (4)	03 Feb 2021 13:59:30



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:05:24
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Generalized pain is included in the AE eCRF page within the date range' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:00:59
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:50:56
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '2'	Riley King (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	03 Feb 2021 13:59:30



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 13:59:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User entered empty.	System	03 Feb 2021 13:59:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User entered empty.	System	03 Feb 2021 13:59:30



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:35
User entered empty.	System	03 Feb 2021 13:59:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
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)	03 Feb 2021 14:54:46
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 14:54:46
Data point term sent to Coder	System	03 Feb 2021 14:01:12
User entered 'Norco 5/325'	Riley King (b) (4)	03 Feb 2021 14:00:14
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:06:34
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Date updated per source information.' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:03:01
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:51:09
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'tablet (TABLET)'	Riley King (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:00:14



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User entered empty.	System	03 Feb 2021 14:00:14

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User entered empty.	System	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:42
User entered empty.	System	03 Feb 2021 14:00:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
User closed query 'please verify if this entry can be merged with line 7' (Site from CRA).	(b) (4)	
Query 'please verify if this entry can be merged with line 7' answered with 'duplicate- inactivated' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:23:25
DataPoint Verified.	marissa Mueller (b) (4)	17 Mar 2021 15:33:57
	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User opened query 'please verify if this entry can be merged with line 7' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 18:01:19
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)	03 Feb 2021 14:54:47
	(b) (4)	
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 14:54:47
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 14:01:10
User entered 'Norco 10/325'	Riley King (b) (4)	03 Feb 2021 14:00:58
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:08:23
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Date updated per source information. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:03:22
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:51:19
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'tablet (TABLET)'	Riley King (b) (4)	03 Feb 2021 14:00:58



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 00:23:16
DataPoint Un-verified.	marissa Mueller (b) (4)	17 Mar 2021 15:34:44
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	17 Mar 2021 15:34:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:00:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User entered empty.	System	03 Feb 2021 14:00:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User entered empty.	System	03 Feb 2021 14:00:58

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:49
User entered empty.	System	03 Feb 2021 14:00:58

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:02:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:02:44
Data point term sent to Coder	System	03 Feb 2021 14:02:13
User entered 'Metoprolol'	Riley King (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'Hypertension'	Riley King (b) (4)	03 Feb 2021 14:01:37



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '50'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'twice daily (BID)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '30 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:01:37

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User entered '2'	System	03 Feb 2021 14:01:37

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User entered '1'	System	03 Feb 2021 14:01:37

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:12:58
User entered '804 (804)'	System	03 Feb 2021 14:01:37

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	04 Feb 2021 10:19:43
	(b) (4)	
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 10:19:43
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 14:04:13
User entered 'Albuterol/ipratropium'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'acute respiratory failure'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '3'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mL (mL)'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'three times daily (TID)'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4), (b) (6)	
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).		17 Feb 2021 13:09:51
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 'Updated per new information in source. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 16:06:47
	(b) (4)	
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 07:51:36
User entered '31 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:03:38
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Feb 2021 14:03:38

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 14:03:38



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 14:03:38

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: LEVALBUTEROL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 10:16:52
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 10:16:52
Data point term sent to Coder	System	03 Feb 2021 14:05:14
User entered 'Levalbuterol HCL'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Acute respiratory failure'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1.25'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'twice daily (BID)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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)	17 Feb 2021 13:10:00
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 'AE start date updated per source.' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:08:00
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 07:52:06
User entered '1 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	18 Mar 2021 00:21:30
User closed query 'please verify if breathing treatments continued past hosp/PT discharge' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:21:24
Query 'please verify if breathing treatments continued past hosp/PT discharge' answered with 'reconciled' (Site from CRA).	Riley King (b) (4)	17 Mar 2021 15:58:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	17 Mar 2021 15:58:22
User opened query 'please verify if breathing treatments continued past hosp/PT discharge' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 18:13:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:21:28
User entered '9 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	17 Mar 2021 15:58:22
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:04:32



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User entered '2'	System	03 Feb 2021 14:04:32

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User entered '1'	System	03 Feb 2021 14:04:32

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:34
User entered '804 (804)'	System	03 Feb 2021 14:04:32

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: SOLVENTS AND DILUTING AGENTS, INCL. IRRIGATING SOLUTIONS, PRODUCT: WATER FOR INJECTION, PRODUCTSYNONYM: BACTERIOSTATIC WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:06:44
Data point term sent to Coder	System	03 Feb 2021 14:06:14
User entered 'Bacteriostatic water'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Fracture of superior rim right pubis'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '12'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mL/hour'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'other (OTHER)'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'Every 6 hours'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '31 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:05:45



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '8 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:05:45

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User entered empty.	System	03 Feb 2021 14:05:45

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User entered empty.	System	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:14:49
User entered empty.	System	03 Feb 2021 14:05:45

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: ESTERS OF AMINOBENZOIC ACID, PRODUCT: BENZOCAINE;MENTHOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:00:51
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:00:51
Data point term sent to Coder	System	03 Feb 2021 14:07:15
User entered 'Benzocaine/menthol'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Fracture or superior rim right pubis'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Other (OTHER)'	Riley King (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Lozenge'	Riley King (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:06:49

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User entered empty.	System	03 Feb 2021 14:06:49

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User entered empty.	System	03 Feb 2021 14:06:49

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:12
User entered empty.	System	03 Feb 2021 14:06:49

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:54:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:54:46
Data point term sent to Coder	System	03 Feb 2021 14:08:15
User entered 'Morphine 4mg/mL'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:10:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Date of AE updated per source. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 16:09:14
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:52:26
User entered 'Generalized pain'	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '4'	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	03 Feb 2021 14:07:42



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:07:42

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User entered empty.	System	03 Feb 2021 14:07:42

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User entered empty.	System	03 Feb 2021 14:07:42



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:27
User entered empty.	System	03 Feb 2021 14:07:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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) (b) (4)	04 Feb 2021 11:50:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:50:44
Data point term sent to Coder	System	03 Feb 2021 14:09:16
User entered 'Zofran 4mg/mL'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Generalized nausea'	Riley King (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '4'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:08:36



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User entered empty.	System	03 Feb 2021 14:08:36

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User entered empty.	System	03 Feb 2021 14:08:36

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:43
User entered empty.	System	03 Feb 2021 14:08:36

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
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)	04 Feb 2021 11:50:16
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 11:50:16
Data point term sent to Coder	System	03 Feb 2021 14:10:16
User entered 'Zofran 4mg/2mL'	Riley King (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'Generalized nausea'	Riley King (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '4'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	03 Feb 2021 14:10:13



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '28 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:10:13

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User entered empty.	System	03 Feb 2021 14:10:13

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User entered empty.	System	03 Feb 2021 14:10:13

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:15:47
User entered empty.	System	03 Feb 2021 14:10:13

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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) (b) (4)	04 Feb 2021 15:00:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 15:00:47
Data point term sent to Coder	System	03 Feb 2021 14:11:17
User entered 'Dilaudid(hydromorphone 0.5mg/0.5mL)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:11:02
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Date of AE updated per source. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:09:41
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:52:37
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0.5'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:11:14



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:11:14

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User entered empty.	System	03 Feb 2021 14:11:14

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User entered empty.	System	03 Feb 2021 14:11:14

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:08
User entered empty.	System	03 Feb 2021 14:11:14

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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) (b) (4)	03 Feb 2021 14:54:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:54:46
Data point term sent to Coder	System	03 Feb 2021 14:12:17
User entered 'Norco 5/325'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:11:09
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'AE date updated per source. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:10:27
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:52:49
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'tablet (TABLET)'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:12:11



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:12:11

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User entered empty.	System	03 Feb 2021 14:12:11

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User entered empty.	System	03 Feb 2021 14:12:11



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:14
User entered empty.	System	03 Feb 2021 14:12:11

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:14:44
Data point term sent to Coder	System	03 Feb 2021 14:14:20
User entered 'Mirtazapine'	Riley King (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
User closed query 'please verify AE of worsening depression from Med Hx (son died per 12Jan21 hosp note' (Site from CRA).	(b) (4)	18 Mar 2021 00:29:38
Query 'please verify AE of worsening depression from Med Hx (son died per 12Jan21 hosp note' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4)	17 Mar 2021 20:19:43
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User opened query 'please verify AE of worsening depression from Med Hx (son died per 12Jan21 hosp note' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:58:37
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for dose increase.	(b) (4), (b) (6)	18 Feb 2021 14:43:34
' (Site from DM).		
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for dose increase.	Cayla Lawless (b) (4)	16 Feb 2021 16:30:24
' answered with 'Dosage increased due to natural progression of disease. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for dose increase.	(b) (4), (b) (6)	12 Feb 2021 07:53:02
' (Site from DM).		
User entered 'Depression'	Riley King (b) (4)	03 Feb 2021 14:13:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '15'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
User closed query 'please verify this date conflicts with line 10 start date' (Site from CRA).	(b) (4)	18 Mar 2021 00:29:52
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 00:29:50
Query 'please verify this date conflicts with line 10 start date' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	17 Mar 2021 20:19:48
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 20:19:17
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 18:13:53
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User opened query 'please verify this date conflicts with line 10 start date' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:56:18
User entered '12 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:13:42



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User entered '1'	System	03 Feb 2021 14:13:42

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User entered '1'	System	03 Feb 2021 14:13:42

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:16:55
User entered '804 (804)'	System	03 Feb 2021 14:13:42

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:10:52
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 09:10:52
Data point term sent to Coder	System	03 Feb 2021 14:15:21
User entered 'Bisacodyl'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Constipation, recurrent'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '5'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '29 Dec 2020'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:14:23

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User entered '1'	System	03 Feb 2021 14:14:23

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User entered '1'	System	03 Feb 2021 14:14:23

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:51
User entered '804 (804)'	System	03 Feb 2021 14:14:23

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 14:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Feb 2021 14:15:44
Data point term sent to Coder	System	03 Feb 2021 14:15:21
User entered 'Tramadol'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:12:39
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'AE date updated to reflect source information.' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:12:18
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:53:19
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:01



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '50'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:01



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:20:14
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '11 Mar 2021' reason for change: New Information	Riley King (b) (4)	15 Mar 2021 19:20:14
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:57:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User entered empty.	System	03 Feb 2021 14:15:01

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User entered empty.	System	03 Feb 2021 14:15:01

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:59
User entered empty.	System	03 Feb 2021 14:15:01

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:53:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:53:45
Data point term sent to Coder	System	03 Feb 2021 14:16:22
User entered 'Lasix(furosemide)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:17:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE date updated per new source information. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 16:14:19
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:53:29
User entered 'Hypoxia'	Riley King (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '20'	Riley King (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '2 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '2 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:15:46

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User entered empty.	System	03 Feb 2021 14:15:46

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User entered empty.	System	03 Feb 2021 14:15:46



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:07
User entered empty.	System	03 Feb 2021 14:15:46

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 14:53:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	03 Feb 2021 14:53:45
Data point term sent to Coder	System	03 Feb 2021 14:17:24
User entered 'Lasix(furosemide)'	Riley King (b) (4)	03 Feb 2021 14:16:24
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:17:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE date updated per new source information. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:14:39
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:53:40
User entered 'Hypoxia'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '20'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once (ONCE)'	Riley King (b) (4)	03 Feb 2021 14:16:24



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '3 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:16:24



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User entered empty.	System	03 Feb 2021 14:16:24

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User entered empty.	System	03 Feb 2021 14:16:24

US3062075

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:12
User entered empty.	System	03 Feb 2021 14:16:24

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:10:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:10:07
Data point term sent to Coder	System	03 Mar 2021 16:02:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:01:37
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:01:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:17:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:17:44
Data point term sent to Coder	System	03 Feb 2021 14:17:22
User entered 'Amlodipine'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:02

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
	(b) (4)	
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:44:02
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'Medication added due to natural progression of disease. ' (Site from DM).	Cayla Lawless (b) (4)	16 Feb 2021 16:30:04
	(b) (4)	
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:53:51
User entered 'Hypertension'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered '5'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'once daily (QD)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered '4 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:17:02
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
User entered 'I'	System	03 Feb 2021 14:17:02

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
User entered 'I'	System	03 Feb 2021 14:17:02

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:37
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	03 Mar 2021 16:01:15
User entered '804 (804)'	System	03 Feb 2021 14:17:02

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
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)	03 Feb 2021 14:55:44
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 14:55:44
Data point term sent to Coder	System	03 Feb 2021 14:18:25
User entered 'Norco 7.5/325'	Riley King (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:18:39
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'AE date updated to reflect the source. ' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 16:16:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication for these dates. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:54:05
User entered 'Generalized pain'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'I'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'tablet (TABLET)'	Riley King (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '1 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:17:40



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '9 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:17:40

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User entered empty.	System	03 Feb 2021 14:17:40

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User entered empty.	System	03 Feb 2021 14:17:40

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:22
User entered empty.	System	03 Feb 2021 14:17:40

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:18:44
Data point term sent to Coder	System	03 Feb 2021 14:18:25
User entered 'Hydralazine'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:16



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Hypertension'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '25'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'as needed (PRN)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '4 Jan 2021'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:18:16
	(b) (4)	

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 14:18:16

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 14:18:16



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 14:18:16

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
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: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:25:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:25:43
Data point term sent to Coder	System	03 Feb 2021 14:19:26
User entered 'Prednisone'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Fracture of superior rim right pubis'	Riley King (b) (4)	03 Feb 2021 14:18:55
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '20'	Riley King (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'once daily (QD)'	Riley King (b) (4)	03 Feb 2021 14:18:55



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '5 Jan 2021'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Riley King (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:28:21
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)	06 Apr 2021 04:25:17
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
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 'updated' (Site from DM).	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:47:25
DataPoint Un-verified.	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:47:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 19:47:14
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) (4), (b) (6)	29 Mar 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:28:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	02 Apr 2021 19:47:14
	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	02 Apr 2021 19:47:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Riley King (b) (4)	03 Feb 2021 14:18:55
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Riley King (b) (4)	03 Feb 2021 14:18:55



**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User entered '1'	System	03 Feb 2021 14:18:55

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User entered '1'	System	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:29
User entered '804 (804)'	System	03 Feb 2021 14:18:55

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:55:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:55:58
Data point term sent to Coder	System	03 Mar 2021 22:46:09
Data point term sent to Coder	System	03 Mar 2021 16:07:09
Data point term sent to Coder	System	03 Mar 2021 16:05:07
User entered 'Bisocodyl'	Sherry Henning (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'constipation, recurrent'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '10'	Sherry Henning (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:06:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 16:06:10
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry Henning (b) (4)	03 Mar 2021 16:06:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Mar 2021 16:04:27
User entered empty.	Sherry Henning (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered 'Rectal (RECTAL)' reason for change:	Riley King (b) (4)	03 Mar 2021 22:45:13
Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:06:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 16:06:10
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Sherry Henning (b) (4)	03 Mar 2021 16:06:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Mar 2021 16:04:27
	Sherry Henning (b) (4)	03 Mar 2021 16:04:27
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '30 Dec 2020'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '30 Dec 2020'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:04:27

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User entered empty.	System	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User entered empty.	System	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:57:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:36
User entered empty.	System	03 Mar 2021 16:04:27

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:40:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	16 Mar 2021 11:40:49
Data point term sent to Coder	System	03 Mar 2021 16:06:08
User entered 'methylprednisolone'	Sherry Henning (b) (4)	03 Mar 2021 16:05:30
	(b) (4)	

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'hypoxia'	Sherry Henning (b) (4)	03 Mar 2021 16:05:30



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '40'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'mg (mg)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:05:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 16:05:43
User entered 'as needed (PRN)' reason for change: Data Entry Error	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:05:30
User entered empty.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'Intravenous (INTRAVENOUS)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered empty.	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '02 Jan 2021' reason for change: Data Entry Error	Sherry Henning (b) (4)	08 Mar 2021 17:22:55
User entered '31 Dec 2020'	(b) (4) Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30



US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4)	16 Mar 2021 18:12:02
User entered '0'	Sherry Henning (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered '04 Jan 2021'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:57:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:12:02
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	03 Mar 2021 16:05:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 14:57:41**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User entered empty.	System	03 Mar 2021 16:05:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User entered empty.	System	03 Mar 2021 16:05:30

**US3062075**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 14:57:41**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:18:42
User entered empty.	System	03 Mar 2021 16:05:30

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:57:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Riley King (b) (4)	03 Feb 2021 13:54:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	01 Sep 2020 23:03:34
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4)	11 Aug 2020 23:08:53



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '1 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:55:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Echo with doppler'	Riley King (b) (4)	03 Feb 2021 13:55:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Adverse Event (AE)'	Riley King (b) (4)	03 Feb 2021 13:55:24
	(b) (4)	

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:55:24
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '2 Jan 2021'	Riley King (b) (4)	03 Feb 2021 13:55:43
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Chest x-ray'	Riley King (b) (4)	03 Feb 2021 13:55:43

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:55:43

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:55:43



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '30 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:56:12

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'chest CT'	Riley King (b) (4)	03 Feb 2021 13:56:12
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:56:12

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:56:12
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '28 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:56:48

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Chest x-ray'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:56:48

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:56:48

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:56:48
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '29 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:16

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered 'Chest x-ray with contrast'	Riley King (b) (4)	03 Feb 2021 13:57:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:16

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	03 Feb 2021 13:57:16
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '29 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:44

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Chest x-ray without contrast'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:44

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Adverse Event (AE)'	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:44

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	03 Feb 2021 13:57:44



US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '16 Jan 2021'	Colton King (b) (4)	24 Feb 2021 14:33:46

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'Physical Therapy'	Colton King (b) (4)	24 Feb 2021 14:33:46

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:44:24
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	17 Mar 2021 20:11:39
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:09:54
User entered 'Adverse Event (AE)'	Colton King (b) (4) (b) (4)	24 Feb 2021 14:33:46

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	(b) (4) Colton King (b) (4)	24 Feb 2021 14:33:46

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:57:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered '16 Jan 2021'	Colton King (b) (4)	24 Feb 2021 14:34:25

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:57:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered 'occupational therapy'	Colton King (b) (4)	24 Feb 2021 14:34:25

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:57:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:44:28
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	17 Mar 2021 20:11:56
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:11:56
User entered 'Adverse Event (AE)'	Colton King (b) (4) (b) (4)	24 Feb 2021 14:34:25

US3062075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:57:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
User entered empty.	Colton King (b) (4)	24 Feb 2021 14:34:25



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered '04/Jan/2021 13:52'	System	04 Jan 2021 13:52:18

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 13:52:18

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '28/Jan/2021 14:22'	System	28 Jan 2021 14:22:43

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 21:10:46
User entered 'I'		28 Jan 2021 14:22:43

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '29/Jan/2021 16:10'	System	29 Jan 2021 21:10:56

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:58:00
User entered 'I'		29 Jan 2021 21:10:56

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '04/Feb/2021 12:58'	System	04 Feb 2021 12:58:11

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:20:38
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 12:58:11



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '17/Feb/2021 10:20'	System	17 Feb 2021 16:20:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:21:31
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 16:20:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '18/Feb/2021 09:28'	System	18 Feb 2021 14:28:58

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:42:56
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 14:28:58

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '25/Feb/2021 13:40'	System	25 Feb 2021 18:40:02

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 17:15:19
User entered 'I'		25 Feb 2021 18:40:02

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '10/Mar/2021 12:15'	System	10 Mar 2021 17:16:16

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:44:06
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 17:16:16



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18



**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (9)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '16/Mar/2021 11:44'	System	16 Mar 2021 15:44:17

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 15:44:17

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (10)**

**Generated On: 09 Jun 2021 14:57:41**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
User entered '18/Mar/2021 07:03'	System	18 Mar 2021 14:03:51

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:57:41

**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 20:25:53
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 14:03:51

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered	System	04 Jan 2021 13:51:52
'USA-US090-2021-MRNA-1273-P301000001'		

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Yes (Y)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'No (N)'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Richard'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Glover'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '700 Medical Center Dr.'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'Newton'	System	04 Jan 2021 13:51:52



US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered 'KS'	System	04 Jan 2021 13:51:52

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:52:12
User entered '67114'	System	04 Jan 2021 13:51:52

US3062075

Folder: SAE USA-US090-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:25:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:22:27
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:06:50
User entered 'US'	System	04 Jan 2021 13:52:18

**US3062075**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:57:41**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	18 Mar 2021 14:03:51
User entered '9'	System	16 Mar 2021 15:44:17
User entered '8'	System	10 Mar 2021 17:16:16
User entered '7'	System	25 Feb 2021 18:40:02
User entered '6'	System	18 Feb 2021 14:28:58
User entered '5'	System	17 Feb 2021 16:20:52
User entered '4'	System	04 Feb 2021 12:58:11
User entered '3'	System	29 Jan 2021 21:10:56
User entered '2'	System	28 Jan 2021 14:22:43
User entered '1'	System	04 Jan 2021 13:52:18