

US3412081 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:30:07

All time stamps listed in this document are displayed in GMT

US3412081

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:13:08

Generated On: 09 Jun 2021 17:30:07

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Participant ID

US3412081

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

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US3412081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" 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



US3412081

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3412081

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	BPH
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

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



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	DIABETES - TYPE 2
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	ADHD
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	CARPAL TUNNEL RIGHT WRIST
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	RIGHT KNEE ACL REPAIR
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	LEFT KNEE ACL REPAIR
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	LEFT INGUINAL HERNIORRHAPHY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	FUCH'S DYSTROPHY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	LEFT TORN ROTATOR CUFF
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Condition	LEFT INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	15:40 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:40
Height ( <i>xxx.x</i> )	172 cm
Weight ( <i>xxx.x</i> )	85.0 kg
BMI ( <i>xxx.x</i> )	28.73175 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 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: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**Specify**

TRAVELS TO (b) (6) AND  
SEES LARGE GROUPS OF  
FAMILY DO NOT WEAR MASKS  
RUNS DAILY ERRANDS

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

**No Risk Identified** False

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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 184375

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) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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)	31 JUL 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:40
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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)	31 JUL 2020
Time of assessment (00:00-23:59)	18:38 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 18:38
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 17:20 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 17:20

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) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	16:27 (24 HR)
Collection date and time (derived)	31 JUL 2020 16:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:21	31 JUL 2020 16:21
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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 17:30:07

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

31 JUL 2020 19:11

PC Open Date & Time

31 JUL 2020 17:40

PC Close Date & Time

31 JUL 2020 20:10

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**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 97.9 °F

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

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

PC Time Stamp 31 JUL 2020 22:43  
PC Open Date & Time 31 JUL 2020 21:05  
PC Close Date & Time 01 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**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

97.7 °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

01 AUG 2020 21:33

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 22:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**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

98.4 °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

03 AUG 2020 21:17

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**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

97.4 °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 21:32

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**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

98.0 °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

05 AUG 2020 21:01

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 21:20

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 19:13

PC Open Date & Time

31 JUL 2020 17:40

PC Close Date & Time

31 JUL 2020 20:10

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**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

31 JUL 2020 22:44

PC Open Date & Time

31 JUL 2020 21:05

PC Close Date & Time

01 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**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

01 AUG 2020 21:35

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**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

02 AUG 2020 22:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**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

03 AUG 2020 21:17

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**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

04 AUG 2020 21:32

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**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

05 AUG 2020 21:02

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**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

06 AUG 2020 21:20

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**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 ☐

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 19:13
PC Open Date & Time	31 JUL 2020 17:40
PC Close Date & Time	31 JUL 2020 20:10

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**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 ☐

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 22:45
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PC Open Date & Time	31 JUL 2020 21:05
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PC Close Date & Time	01 AUG 2020 11:59
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US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**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 ☒

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:36
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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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EAB) (1725)

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 22:08
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 3900

EAB) (1725)

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:18
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:33
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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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US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:02
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

US3412081

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:30:07

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 AUG 2020 21:06
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:26:20

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3412081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:26:20

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:26:20

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:26:20

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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

Visit date (dd MMM yyyy)	31 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:00
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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)	31 AUG 2020
Time of assessment (00:00-23:59)	15:13 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 15:13
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 14:40

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

What was the frequency of the study treatment dosing? ONCE

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



US3412081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

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

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	14:13 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	31 AUG 2020 14:13
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US3412081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:08	31 AUG 2020 14:08
Nasopharyngeal Swab 2	No		

US3412081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

31 AUG 2020 15:01

PC Open Date & Time

31 AUG 2020 15:00

PC Close Date & Time

31 AUG 2020 17:30

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 21:08

PC Open Date & Time

31 AUG 2020 18:25

PC Close Date & Time

01 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**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

97.7 °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

01 SEP 2020 21:09

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:23

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**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

97.7 °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 SEP 2020 21:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**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

96.4 °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

05 SEP 2020 21:37

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:18

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**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

31 AUG 2020 15:03

PC Open Date & Time

31 AUG 2020 15:00

PC Close Date & Time

31 AUG 2020 17:30

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**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

31 AUG 2020 21:10

PC Open Date & Time

31 AUG 2020 18:25

PC Close Date & Time

01 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**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

01 SEP 2020 21:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**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

02 SEP 2020 20:55

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**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

03 SEP 2020 21:24

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**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

04 SEP 2020 21:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**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

05 SEP 2020 21:38

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**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

06 SEP 2020 22:18

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**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 ☐

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 15:03
PC Open Date & Time	31 AUG 2020 15:00
PC Close Date & Time	31 AUG 2020 17:30

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**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 ☐

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 21:11
PC Open Date & Time	31 AUG 2020 18:25
PC Close Date & Time	01 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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)

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:55
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:24
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

115 of 3900

EAB) (1725)



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:38
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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 ☒

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:19
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:26:21

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:26:20

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:33:01

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:33:01

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3412081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:33:08

Generated On: 09 Jun 2021 17:30:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT3

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:33:08

Generated On: 09 Jun 2021 17:30:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:33:08

Generated On: 09 Jun 2021 17:30:07

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.*

US3412081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

28 SEP 2020 13:30

US3412081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:33:07

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 SEP 2020 15:16:36
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

07 OCT 2020 19:34:53

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59



US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 11:56:07
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

28 OCT 2020 20:59:06

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 21:37:09
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

11 NOV 2020 07:10:35

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 113
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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 NOV 2020 01:28:35
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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	29 NOV 2020 16:56:26
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 17:12:14

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

15 DEC 2020 14:33:48

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59
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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

28 DEC 2020 18:12:21

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

03 JAN 2021 10:11:11

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 07:19:32
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

17 JAN 2021 08:40:37

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

26 JAN 2021 22:24:01

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

01 FEB 2021 07:02:08

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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 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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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18 FEB 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

22 FEB 2021 14:34:52

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

01 MAR 2021 21:21:54

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

07 MAR 2021 00:42:44

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 12:30:48
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 MAR 2021 23:53:06
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

31 MAR 2021 17:26:48

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

11 APR 2021 15:05:15

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

18 APR 2021 22:42:26

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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

26 APR 2021 10:30:53

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 MAY 2021 10:17:54
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 299

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐ Yes ☐

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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="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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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 <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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 509

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 516

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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°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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

13 MAR 2022 00:01

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17 MAR 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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 ☐ Yes ☐

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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27 MAR 2022 00:01

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31 MAR 2022 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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07 APR 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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21 APR 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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="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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

24 APR 2022 00:01

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28 APR 2022 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

15 MAY 2022 00:01

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19 MAY 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUN 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59



US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**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 ☐

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

US3412081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

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°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"/>

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3412081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:30:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 21:22:07

US3412081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3412081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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*

US3412081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

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

Visit date (dd MMM yyyy)	23 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"/>

Folder OID	VISIT4
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US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	12:58 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:58
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3412081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

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

Collection date (dd MMM yyyy)	23 FEB 2021
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Collection time (00:00-23:59)	11:22 (24 HR)
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Collection date and time (derived)	23 FEB 2021 11:22
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US3412081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:11

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3412081**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

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*

**US3412081**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3412081**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:30:07**

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"/>

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3412081

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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

Visit date (dd MMM yyyy)	18 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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US3412081

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Date of updated informed consent ( <i>dd MMM yyyy</i> )	18 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> )	18 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

US3412081

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Height	172.5 cm
Weight	73.6 kg
BMI (xxx.x)	24.73430

US3412081

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Height	172.5 cm
Weight	73.6 kg
BMI (xxx.x)	24.73430
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:20
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412081

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Height	172.5 cm
Weight	73.6 kg
BMI (xxx.x)	24.73430
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 13:00
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412081

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

22 JAN 2021

---

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

---



US3412081

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 12:27

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

What was the frequency of the study treatment dosing? ONCE

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

US3412081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00-23:59)	12:20 (24 HR)
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Collection date and time (derived)	18 JAN 2021 12:20
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US3412081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	11:15
Collection Date and Time (derived)	18 JAN 2021 11:15

US3412081

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

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

US3412081

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3412081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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)	23 FEB 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 11:19
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG



US3412081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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)	23 FEB 2021
Time of assessment (00:00-23:59)	12:58 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:58
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412081

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3412081

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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) 23 FEB 2021

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 12:27

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

What was the frequency of the study treatment dosing? ONCE

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

US3412081

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412081

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:29:43

Generated On: 09 Jun 2021 17:30:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412081

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412081

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:12 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 10:12
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3412081

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

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.*

US3412081

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:13:10

Generated On: 09 Jun 2021 17:30:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	10:28 (24 HR)
Collection date and time (derived)	24 MAR 2021 10:28

US3412081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:28:40

Generated On: 09 Jun 2021 17:30:07

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3412081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID	USA-US061-2020-MRNA-1273-P30 1000012
Adverse event	PNEUMONIA DUE TO GRAM NEGATIVE KLEBSIELLA BACTERIA
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)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

	Unknown	<input type="radio"/>
Number of Days in ICU		4
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		

US3412081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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PATIENTS WIFE CALLED TO  
REPORT PATIENT ADMITTED  
ON 11/13 FOR COUGH AND  
FATIGUE. WORKUP REVEALED  
PNEUMONIA AND NEGATIVE  
COVID-19 RESULTS. PATIENT  
WAS IN ICU 11/14/20 TO 11/17/20  
AND HAS RECEIVED  
ANTIBIOTIC. PATIENT WAS  
ADMITTED TO MERCY  
ANDERSON HOSPITAL.  
PATIENT IS EXPERIENCING  
DAILY IMPROVEMENT. AN  
X-RAY OF THE CHEST WAS  
COMPLETED AND LOW LONG  
VOLUMES, THAT IS  
PERSISTENT BIBASILAR  
AIRSPACE DISEASE  
REPRESENTING PNEUMONIA.  
CT OF THE CHEST, ABDOMIN,  
AND PELVIS WHERE  
SIGNIFICANT BILATERAL  
LOWER LOBE ATELECTASIS  
AND CONSOLIDATION WAS  
FOUND, WITH TRACE  
BILATERAL PLEURAL  
EFFUSIONS. ANOTHER CHEST  
X-RAY WHERE LEFT BASILAR  
AIRSPACE AND TRACE  
EFFUSION SUSPECTED AND  
PULMONARY VASCULAR  
CONGESTION. SUBJECT ALSO  
HAD A CT OF THE ABDOMEN  
WITH FINDINGS CONSISTENT  
WITH PANCREATITIS WITH AN

US3412081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

---

EDEMATOUS APPEARING  
PANCREAS WITH  
PERIPANCREATIC FLUID SEEN.  
LARGE HYPODENSITY AGAIN  
SEEN IN THE LIVER WITH  
AREAS OF HEMORRHAGE  
WHICH REMAIN WITHOUT  
CHANGE. A CT ABSCESS  
DRAINAGE WITH CATH  
PLACEMENT WITH A FINDING  
OF A LARGE HYPODENSE  
COLLECTION SEEN IN THE  
LIVER. WITH AREAS OF  
INCREASED DENSITY SEEN  
WITHIN THE COLLECTION  
SUSPECTED TO BE  
PSEUDOANEURYSMS EITHER  
RELATED PORTAL  
COLLATERALS VERSUS  
HEPATIC VEIN. A LARGE  
HEPATIC LESION. AN MRI OF  
THE ABDOMEN WIHT  
FINIDINGS OF INTERSTITIAL  
EDEMATOUS PANCREATITIS  
MOST PROMINENT IN THE  
PANCREATIC UNCINATE  
PROCESS, HEAD, AND NECK. A  
FINDING OF CHOLELITHIASIS  
AND BILIARY SLUDGE WITHIN  
THE GALLBLADDER, A NEW 7.9  
CM X 10.6 CM X 5.4 CM LESION,  
AND TRACE ASCITES SMALL  
TO MODERATE RIGHT PLURAL  
EFFUSION, AND PASSIVE  
ATELECTASIS IN EACH LUNG

US3412081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

---

BASE. A US GALLBLADED RUQ  
WITH A SMALL AMOUNT OF  
SLUDGE WAS SEEN. A CT  
ABDOMEN PELVIS WITH IV  
CONTRAST WHERE ACUTE  
PANCREATITIS WITH SEVER  
INFLAMMATION AROUND THE  
HEAD AND BODY OF THE  
PANCREAS WAS FOUND AND  
PERIPORTAL EDEMA IS LIKELY  
SECONDARY TO THE ABOVE  
FINDINGS.

COVID RT PCR LAB RESULTS:  
NOT DETECTED ON 01/07/21  
AND 11/15/20

---

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

---



US3412081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID

Adverse event

ACUTE BILIARY PANCREATITIS

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)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 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 (2)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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

US3412081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID	USA-US061-2020-MRNA-1273-P30 1000012
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)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	26 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

US3412081

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID

Adverse event

ACUTE KIDNEY INJURY

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)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412081

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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 (6)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID

Adverse event

LIVER HEMATOMA

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)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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 (7)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID

Adverse event

KLEBSIELLA GRAM NEGATIVE  
BACTEREMIA

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)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID

Adverse event

SYSTEMIC INFLAMMATORY  
RESPONSE SYNDROME

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)

20 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID	
Adverse event	HEART 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)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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 (9)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID	USA-US061-2020-MRNA-1273-P30 1000012
Adverse event	CHOLECYSTITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 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)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	13 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 (10)

Data signed: (b) (4) 28 Apr 2021 21:46:22

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



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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 21:46:22

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HOSPITALIZATION FOR  
KLEBSIELLA PNEUMONIA  
13NOV2020 W/ ACUTE BILIARY  
PANCREATITIS, ACUTE KIDNEY  
INJURY, AND RESPIRATORY  
FAILURE. S/P LAPAROSCOPIC  
CHOLECYSTECTOMY  
13JAN2021 AS OUTPATIENT  
PROCEDURE DID NOT REMAIN  
IN HOSPITAL OVERNIGHT.

SUBJECT PRESENTED TO  
MERVY HEALTH AS A 72 Y/O  
MALE FOR  
ROBOTIC/LAPROSCOPIC  
CHOLECYSTECTOMY D/T  
CHOLECYSTITIS ON 13JAN2021.  
SURGERY WAS UNEVENTFUL  
AND SUBJECT WAS  
DISCHARGED SAME DAY.  
ROUTINE LABS WERE  
OBTAINED AND WERE WITHIN  
NORMAL LIMITS. MEDS GIVEN  
DURING STAY: BUPIVACANE -  
EPINEPHERINE 0.5% 20 ML  
INTRAPHEURAL, CETTNAXINE  
2G IV, DECADRON 4MG IV,  
EPHEDRINE 10MG IB,  
EPHEDRINE 20MG IV,  
EPINEPHRINE 1MG/1ML 10 MCG  
IV, FENTANYL 50 MCG IV,  
GLYCOPYCOLATE .2 MG IV,  
INDOCYANINE GREEN 12.5MG  
IV, LIDOCAINE 2% 50MG IV,  
FLAGYL 500MG IV, ZOFRAN

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 21:46:22

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4MG IV, PHEYLEPHRINE 80MCG  
IV, PHENYLEPHRINE 160 MCG  
IV, PROPROFOL 140 MCG IV,  
ZEMURON 20 MG IV, ZEMURON  
50MG IV, DILAUDID .5MG IV,  
BENADRUL 12.5MG IV,  
LABETOLOL 5MG IV,  
APRESOLINE 5MG IV,  
OXYCODONE 5MG PO PAIN,  
OXYCODONE 10MG PO PAIN,  
METOCLOPRAMIDE 10MG IV,  
PHENERGAN 6,25MG IV,  
MORPHINE 1MG IV, BRIDION  
200MG IV, COLACE 100MG BID.

SUBJECT HAS RECOVERED TO  
BASELINE SINCE SURGERY  
AND IS DOING WELL.

---

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 (11)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

AEID	
Adverse event	MELANOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 (11)

Data signed: (b) (4) 28 Apr 2021 21:46:22

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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) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 21:46:22

Generated On: 09 Jun 2021 17:30:07

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:32:39

Generated On: 09 Jun 2021 17:30:07

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

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)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2018		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication LOSARTAN/HCTZ

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100/25

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 (2)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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 (3)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (4)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication TRAZODONE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication AMPHETAMINE

Prophylaxis Yes ☐  
No ☒

Indication ADHD

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 (7)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ALFUZOSIN

Prophylaxis Yes ☐  
No ☒

Indication BPH

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 (8)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐  
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication CARPEL TUNNEL

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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 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)		20 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH PREVENTION

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 (11)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intraocular	<input type="radio"/>
	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE /  
HYPERTENSION

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 (12)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ZOSYN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE BILLARY  
PANCREATITIS

Dose per administration 4/0.5

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 (13)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 DEC 2020	
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 (14)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication LIDOCAINE (4% PATCH))

Prophylaxis Yes ☐  
No ☒

Indication SURGICAL PAIN

Dose per administration 4

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

If dose unit is Other, specify TOPICAL PATH

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication OXYCODINE

Prophylaxis Yes ☐  
No ☒

Indication SURGICAL PAIN

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 (15)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

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 (16)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication POTASSIUM CHLORIDE (MCG)

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 20

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
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 (19)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication DUTASTERIDE

Prophylaxis Yes ☐  
No ☒

Indication BPH

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 (19)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
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) 16 Apr 2021 14:13:09

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Name of Medication DUREZOL (0.05%)

Prophylaxis Yes ☐  
No ☒

Indication POST-OP AND CORNEAL  
TRANSPLANT - ANTI  
REJECTION. OCULAR  
INFLAMATION

Dose per administration 0.05

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify ONE GTT OU

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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Name of Medication ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE BILIARY PACREATITIS /  
PNEUMONIA / KLEBSIELLA  
GRAM NEGATIVE BACTEREMIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (22)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FLAGYL

Prophylaxis Yes ☐  
No ☒

Indication ACUTE BILLARY PACREATITIS /  
PNEUMONIA / KLEBSIELLA  
GRAM NEGATIVE BACTEREMIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (23)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 0-6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
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 (24)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 0-3

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 (24)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA / PANCREATITIS /  
KLEBSIELLA GRAM NEGATIVE  
BACTEREMIA

Dose per administration 3.375/50

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

If dose unit is Other, specify G/ML

Frequency once daily ☐  
twice 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 (25)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPOMAGNESEMIA

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 (26)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication SEDATION FOR SURGICAL  
PROCEDURE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication SEDATION FOR SURGICAL  
PROCEDURE

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 (28)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FENTANYL (MCG)

Prophylaxis Yes ☐  
No ☒

Indication SEDATION FOR SURGICAL  
PROCEDURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FENTANYL (MCG

Prophylaxis Yes ☐  
No ☒

Indication SEDATION FOR SURGICAL  
PROCEDURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication BUPIVACINE-EPINEPHRINE .5/20

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

Dose per administration 1

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

If dose unit is Other, specify INJ

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRAPLEURAL
Start date (dd MMM yyyy)	13 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)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS

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 (33)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)		13 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 (34)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication DECADRON

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS/CHOLECYSTE  
CTOMY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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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)	13 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)		13 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 (35)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication EPHEDRINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (35)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)	13 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 (36)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication EPHEDRINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (36)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)	13 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 (37)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication EPINEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 10

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

If dose unit is Other, specify MCG/ML

Frequency once daily ☐  
twice 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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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) 13 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 (38)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication SEDATION/CHOLECYSTECTOMY

Dose per administration .05

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 16 Apr 2021 14:13:09

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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)	13 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)		13 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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication GLYCOPYROLATE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (39)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication INDOCYANINE GREEN

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 12.5

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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (41)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FLAGYL

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTITIS/  
CHOLECYSTECTOMY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)		13 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 (43)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA/CHOLECYSTECTOMY

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 (43)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PHENYLPHRINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)	13 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 (45)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication SEDATION/CHOLECYSTECTOMY

Dose per administration 140

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)		13 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 (47)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ZEMURON

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (47)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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) 13 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 (48)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLACTIC

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 (48)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication ZEMURON

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (49)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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 (50)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 12.5

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 (50)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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) 13 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 (51)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication LABETALOL

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (51)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication APRESOLINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (52)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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) 13 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication DILLAUDIOL

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (53)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)		13 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 (54)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (54)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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) 13 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 (55)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

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 (55)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 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)		13 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"/>

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication METOCLOPRAMIDE

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA/CHOLECYSTECTOMY

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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EAB) (1725)

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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"/>

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication PHENERGAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA/ CHOLECYSTECTOMY

Dose per administration 6.25

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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"/>

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication CHOLECYSTECTOMY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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"/>

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication PAIN, CHOLECYSTECTOMY

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 (59)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)	13 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)		13 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 (60)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication BRIDION

Prophylaxis Yes ☐  
No ☒

Indication ANETHESIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	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)		13 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)		13 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 (61)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

Name of Medication COLACE

Prophylaxis Yes ☒  
No ☐

Indication CONSTIPATION PROPHYLAXIS

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 (61)

Data signed: (b) (4) 16 Apr 2021 14:13:09

Generated On: 09 Jun 2021 17:30:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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) 13 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 NOV 2020	HEPATIC ANGIO	Adverse Event	
19 NOV 2020	HEPATIC AV FISTULA EMBOLIZATION	Adverse Event	
20 NOV 2020	CT GUIDED CHOLECYSTOSTAMY DRAIN	Adverse Event	
25 NOV 2020	PICCLINE	Adverse Event	
18 NOV 2020	MRCP	Adverse Event	
22 NOV 2020	CARDIAC ECHO	Adverse Event	
24 NOV 2020	CT GUIDED CHOLECYSTOSTAMY DRAIN - UPSIZED DRAIN REVISION	Adverse Event	
22 NOV 2020	ECG	Adverse Event	
13 NOV 2020	ECG	Adverse Event	
14 NOV 2020	CTAB / PELVIS WITH CONTRAST	Adverse Event	
15 NOV 2020	CTAB / PELVIS W/O CONTRAST	Adverse Event	
19 NOV 2020	CTAB WITH CONTRAST	Adverse Event	
21 NOV 2020	CTA CHEST	Adverse Event	
24 NOV 2020	CTA / P / C	Adverse Event	
14 NOV 2020	RUQ ULTRASOUND	Adverse Event	
14 NOV 2020	CXR	Adverse Event	
19 NOV 2020	CXR	Adverse Event	
24 NOV 2020	CXR	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Data signed: (b) (4) 12 Apr 2021 14:32:40

Generated On: 09 Jun 2021 17:30:07

---

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	CHOLECYTECTOMY	Adverse Event	
21 NOV 2020	MRI OF ABD W/O CONTRAST	Adverse Event	
21 NOV 2020	MRI OF ABD W CONTRAST	Adverse Event	

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:30:07

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:30:07

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 ☐

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:24
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/DEC/2020 14:21
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	05/JAN/2021 14:45
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



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/FEB/2021 22:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	18/FEB/2021 08:54
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:24
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	03/MAR/2021 12:01
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:24
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	19/MAR/2021 11:40
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	14/APR/2021 12:31
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

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	19/APR/2021 06:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (12)

Data signed: (b) (4) 28 Apr 2021 21:46:23

Generated On: 09 Jun 2021 17:30:07

SAEID	USA-US061-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	28/APR/2021 09:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412081 (Prod: New Horizons Clinical Research)

**US3412081**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:30:07**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'US3412081'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:44:15

US3412081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:25:27

**US3412081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:44:15

**US3412081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[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 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:25:27

**US3412081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'SCRN'	System	31 Jul 2020 21:25:27

US3412081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:44:16



**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '72'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'YEARS'	System	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '72'	System	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20



**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

**US3412081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:30:07**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:26:20

US3412081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jul 2020'	System	31 Jul 2020 21:27:22



**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2020'	System	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:22

US3412081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:22

**US3412081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:30:07**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 19:34:52
User entered 'Yes (Y)'		31 Jul 2020 21:27:22

US3412081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4)	05 Aug 2020 19:34:52
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	31 Jul 2020 21:27:22
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 19:44:15

US3412081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'I'	System	31 Jul 2020 21:27:32



**US3412081**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:30:07**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:27:32

**US3412081**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:30:07**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:31:57

US3412081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
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.	Coder Import (b) (4)	07 Aug 2020 14:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:17
Data point term sent to Coder	System	07 Aug 2020 14:32:53
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:27



**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2010'	System	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2010'	System	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:27

**US3412081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:27

US3412081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:18
Data point term sent to Coder	System	07 Aug 2020 14:32:56
User entered 'Hypertension'	(b) (4), (b) (6)	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:40



**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2010'	System	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2010'	System	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:40

**US3412081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:40

US3412081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:17
Data point term sent to Coder	System	07 Aug 2020 14:32:56
User entered 'GERD'	(b) (4), (b) (6)	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:53



**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2010'	System	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2010'	System	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:53

**US3412081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:32:53



US3412081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:34:19
Data point term sent to Coder	System	07 Aug 2020 14:33:57
User entered 'BPH'	(b) (4), (b) (6)	07 Aug 2020 14:33:09

US3412081

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2012'	System	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2012'	System	07 Aug 2020 14:33:09



**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:09

**US3412081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:09

US3412081

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:01:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:01:14
Data point term sent to Coder	System	07 Aug 2020 14:34:00
User entered 'Osteoarthritis Knees, hips, back'	(b) (4), (b) (6)	07 Aug 2020 14:33:34

US3412081

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:34



**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2013'	System	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2013'	System	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:34

**US3412081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:34

US3412081

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 17:27:15
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'well controlled without medications' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	01 Oct 2020 14:53:45
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 09:59:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:21
Data point term sent to Coder	System	07 Aug 2020 14:33:58
User entered 'Diabetes - Type 2'	(b) (4), (b) (6)	07 Aug 2020 14:33:57

US3412081

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:57



**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2019'	System	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2019'	System	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:57

**US3412081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:33:57

US3412081

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:37:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:37:14
Data point term sent to Coder	System	07 Aug 2020 14:35:01
User entered 'Insomnia '	(b) (4), (b) (6)	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:18



**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2015'	System	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2015'	System	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:34:18

**US3412081**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:34:18



US3412081

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:37:12
Data point term sent to Coder	System	07 Aug 2020 14:35:00
User entered 'ADHD'	(b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2010'	System	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2010'	System	07 Aug 2020 14:34:30



**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:34:30

**US3412081**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	07 Aug 2020 14:34:30

US3412081

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:57:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:57:35
Data point term sent to Coder	System	17 Sep 2020 19:46:52
Coding entries removed.	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:46:25
User entered 'CARPAL TUNNEL right wrist' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:46:25
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 18:16:47
Data point term sent to Coder	System	17 Sep 2020 18:16:04
User entered 'CARPAL TUNNEL'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'UN UNK 2017'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:15:13



**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2017'	System	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2017'	System	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	17 Sep 2020 18:15:13

**US3412081**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered empty.	System	17 Sep 2020 18:15:13

US3412081

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		16 Mar 2021 05:46:39
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'condition has been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:51:26
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:51:08
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal transplant, LLT: Corneal transplant - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:34:47
Data point term sent to Coder	System	12 Feb 2021 16:34:31
User entered 'bilateral corneal transplant'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 2018'	Andrea Newlands (b) (4)	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:33:32



**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 2018'	Andrea Newlands (b) (4)	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2018'	System	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2018'	System	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2018'	System	12 Feb 2021 16:33:32

**US3412081**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2018'	System	12 Feb 2021 16:33:32

US3412081

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		16 Mar 2021 05:47:16
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'condition has been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:51:36
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:51:25
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:34:48
Data point term sent to Coder	System	12 Feb 2021 16:34:31
User entered 'left rotator cuff repair'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un Jun 2020'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:13



**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un Jun 2020'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jun 2020'	System	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2020'	System	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jun 2020'	System	12 Feb 2021 16:34:13

**US3412081**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2020'	System	12 Feb 2021 16:34:13



US3412081

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		16 Mar 2021 05:47:28
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'condition has been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:51:44
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:51:39
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:35:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 16:35:48
Data point term sent to Coder	System	12 Feb 2021 16:35:32
User entered 'right rotator cuff repair'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:34:47

US3412081

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 2013'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 2013'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2013'	System	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2013'	System	12 Feb 2021 16:34:47



**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2013'	System	12 Feb 2021 16:34:47

**US3412081**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2013'	System	12 Feb 2021 16:34:47

US3412081

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Anterior cruciate ligament reconstruction - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:35:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:35:47
Data point term sent to Coder	System	12 Feb 2021 16:35:32
User entered 'right knee acl repair'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09

US3412081

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1987'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1987'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:35:09



**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1987'	System	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1987'	System	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1987'	System	12 Feb 2021 16:35:09

**US3412081**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1987'	System	12 Feb 2021 16:35:09

US3412081

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Anterior cruciate ligament reconstruction - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:40:47
Data point term sent to Coder	System	12 Feb 2021 16:40:36
User entered 'left knee acl repair'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26

US3412081

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1991'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26



**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1991'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1991'	System	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1991'	System	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1991'	System	12 Feb 2021 16:40:26

**US3412081**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1991'	System	12 Feb 2021 16:40:26

US3412081

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		16 Mar 2021 05:46:57
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'condition has been added into med history' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 20:51:53
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:51:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal herniorrhaphy - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 16:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Feb 2021 16:42:47
Data point term sent to Coder	System	12 Feb 2021 16:41:39
User entered 'left inguinal herniorrhaphy'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28

US3412081

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:30:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1992'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28



**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'un UNK 1992'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1992'	System	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1992'	System	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1992'	System	12 Feb 2021 16:41:28

**US3412081**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1992'	System	12 Feb 2021 16:41:28



US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 20:49:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 20:49:34
Data point term sent to Coder	System	15 Mar 2021 20:49:22
Data point term sent to Coder	System	15 Mar 2021 20:49:21
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 20:49:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 20:49:20
User entered 'right torn rotator cuff' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
Data point term sent to Coder	System	12 Feb 2021 16:43:40
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 16:42:48
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 16:42:48
Data point term sent to Coder	System	12 Feb 2021 16:42:40
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered 'cholecystectomy'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	15 Mar 2021 20:49:20
User entered 'un UNK 2013' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	12 Feb 2021 16:42:18
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	12 Feb 2021 16:42:18
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 16:42:18
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	12 Feb 2021 16:41:54
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Mar 2021 20:49:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 20:49:20
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 16:42:18
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 16:42:18
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un UNK 2013' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 16:42:18
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2013'	System	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	(b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered empty.	System	12 Feb 2021 16:42:18
User entered 'Jan 2021'	System	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2013'	System	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	(b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered empty.	System	12 Feb 2021 16:42:18
User entered '2021'	System	12 Feb 2021 16:41:54



US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2013'	System	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	(b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered empty.	System	12 Feb 2021 16:42:18
User entered 'Jan 2021'	System	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:30:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2013'	System	15 Mar 2021 20:49:20
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 20:48:31
DataPoint inactivated with code reason code Data not required.	(b) (4)	12 Feb 2021 16:42:56
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:35
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 16:42:30
User entered empty.	System	12 Feb 2021 16:42:18
User entered '2021'	System	12 Feb 2021 16:41:54

US3412081

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Eye disorders congenital, HLT: Corneal and scleral disorders congenital, PT: Corneal dystrophy, LLT: Fuchs' endothelial dystrophy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:49:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:49:33
Data point term sent to Coder	System	15 Mar 2021 20:49:19
User entered 'Fuch's Dystrophy'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un UNK 2015'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'No (N)'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un UNK 2018'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:48:23



**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2015'	System	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2015'	System	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 2018'	System	15 Mar 2021 20:48:23

**US3412081**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2018'	System	15 Mar 2021 20:48:23

US3412081

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:30:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:50:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:50:33
Data point term sent to Coder	System	15 Mar 2021 20:50:22
User entered 'Left torn rotator cuff'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un Jun 2020'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'No (N)'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01



**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un Jun 2020'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jun 2020'	System	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2020'	System	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jun 2020'	System	15 Mar 2021 20:50:01

**US3412081**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '2020'	System	15 Mar 2021 20:50:01

US3412081

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:30:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:51:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:51:32
Data point term sent to Coder	System	15 Mar 2021 20:51:24
User entered 'Left inguinal hernia'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un UNK 1992'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35



**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'No (N)'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'un UNK 1992'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1992'	System	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1992'	System	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'Jan 1992'	System	15 Mar 2021 20:50:35

**US3412081**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '1992'	System	15 Mar 2021 20:50:35



US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '15:40'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '31 Jul 2020 15:40'	System	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '172' cm	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07
DataPoint set to visible.	System	31 Jul 2020 21:27:32

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '85.0' kg	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07
DataPoint set to visible.	System	31 Jul 2020 21:27:32

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
Amendment Manager: User entered '28.73175'	System	16 Sep 2020 23:40:01
User entered '28.7'	System	07 Aug 2020 14:36:07
DataPoint set to visible.	System	31 Jul 2020 21:27:32

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'kg/m2'	System	07 Aug 2020 14:36:07
DataPoint set to visible.	System	31 Jul 2020 21:27:32



US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:37:18
User entered '36.3' C		07 Aug 2020 14:36:07

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	17 Aug 2020 20:36:28
Query 'Data is required. Please provide.' answered with 'N/A' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 16:45:17
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 16:37:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:37:18
User entered 'Oral (Oral)'		07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:37:18
User entered '80'		07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'bpm'	System	07 Aug 2020 14:36:07

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Aug 2020 16:37:18
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 14:36:07

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'breaths/min'	System	07 Aug 2020 14:36:07

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Aug 2020 16:37:18
User entered '152'	(b) (4), (b) (6)	07 Aug 2020 14:36:07



**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'mmHg'	System	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:37:18
User entered '94'	(b) (4), (b) (6)	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'mmHg'	System	07 Aug 2020 14:36:07

**US3412081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46

US3412081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46

**US3412081**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:20

US3412081

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 18:27:44
User entered '31 Jul 2020'	(b) (4), (b) (6)	07 Aug 2020 14:35:20

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17



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Folder: Screening

Form: Risk of Exposure

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

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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)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 18:19:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:37:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'TRAVELS TO (b) (6) AND SEES LARGE GROUPS OF FAMILY DO NOT WEAR MASKS RUNS DAILY ERRANDS' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:19:15
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:37:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17



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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '1' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 18:19:15
User entered '0'	Mylene Asmar-Rios (b) (4), (b) (6)	07 Aug 2020 14:37:17

US3412081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '0' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 18:19:35
User entered '1'	Mylene Asmar-Rios (b) (4), (b) (6)	07 Aug 2020 14:37:17

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User closed query 'Location and Living Circumstances Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	(b) (4)	17 Sep 2020 18:19:35
User opened query 'Location and Living Circumstances Risk is recorded as OTHER, but specification was not provided. Please provide.' (Site from System).	System	17 Sep 2020 18:19:15
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 18:19:15
User entered 'Travels to visit large groups of family in (b) (6) with no masks'	(b) (4), (b) (6)	07 Aug 2020 14:37:17

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:28:04

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:28:04

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:28:04

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'VISIT1'	System	31 Jul 2020 21:28:04



US3412081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:09:11

US3412081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:33:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:33:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 21:09:11
User entered '184375' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:09:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 21:09:11

US3412081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

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)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:02

US3412081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

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)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:02

US3412081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 18:40:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 18:40:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 18:40:23
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Jul 2020 21:32:02
User entered empty.	(b) (4), (b) (6)	31 Jul 2020 21:32:02

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:30:07**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:02

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:30:07**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:02



US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	12 Aug 2020 16:40:42
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:40:42
User entered empty.		07 Aug 2020 14:38:42

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '15:40' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:40:42
User entered empty.		07 Aug 2020 14:38:42



**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Jul 2020 15:40'	System	12 Aug 2020 16:40:42
User entered empty.	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '36.3' C reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:40:42
User entered empty.		07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	12 Aug 2020 16:40:42
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '80' reason for change: Data Entry Error	(b) (4)	12 Aug 2020 16:40:42
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'bpm'	System	12 Aug 2020 16:40:42
User entered empty.	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '16' reason for change: Data Entry Error	(b) (4)	12 Aug 2020 16:40:42
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'breaths/min'	System	12 Aug 2020 16:40:42
User entered empty.	System	07 Aug 2020 14:38:42



**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '152' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:40:42
User entered empty.		07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	12 Aug 2020 16:40:42
User entered empty.	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 16:40:42
User entered empty.		07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	12 Aug 2020 16:40:42
User entered empty.	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:30:07**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42



US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '18:38'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Jul 2020 18:38'	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '64'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'bpm'	System	07 Aug 2020 14:38:42



US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'breaths/min'	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '140'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '88'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:38:42

US3412081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	07 Aug 2020 14:38:42

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:10

US3412081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:35:10



US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

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)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '17:20'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Jul 2020 17:20'	System	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	31 Jul 2020 21:32:56



US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'ONCE'	System	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 21:32:56

US3412081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:46

US3412081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:46

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '16:27'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:46

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Jul 2020 16:27'	System	07 Aug 2020 14:37:46

US3412081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:30:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		07 Aug 2020 14:37:59



US3412081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '16:21'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Jul 2020 16:21'	System	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		07 Aug 2020 14:37:59

US3412081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:37:59

**US3412081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered empty.	System	07 Aug 2020 14:37:59

US3412081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:34:57



**US3412081**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	07 Aug 2020 14:34:57

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:11:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6a1be105-24da-4cb8-aef5-89b262053883'	System	31 Jul 2020 23:11:52
User entered 'Yes (Y)'	System	31 Jul 2020 23:11:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:11:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6a1be105-24da-4cb8-aef5-89b262053883'	System	31 Jul 2020 23:11:52
User entered '97.7'	System	31 Jul 2020 23:11:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:11:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6a1be105-24da-4cb8-aef5-89b262053883'	System	31 Jul 2020 23:11:52
User entered 'No (N)'	System	31 Jul 2020 23:11:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:11:47', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6a1be105-24da-4cb8-aef5-89b262053883'	System	31 Jul 2020 23:11:52
User entered '31 Jul 2020 19:11'	System	31 Jul 2020 23:11:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 17:40'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 20:10'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:43:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e587bb65-f594-4baa-a611-37cc01555281'	System	01 Aug 2020 02:43:52
User entered 'Yes (Y)'	System	01 Aug 2020 02:43:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:43:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e587bb65-f594-4baa-a611-37cc01555281'	System	01 Aug 2020 02:43:52
User entered '97.9'	System	01 Aug 2020 02:43:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:43:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e587bb65-f594-4baa-a611-37cc01555281'	System	01 Aug 2020 02:43:52
User entered 'No (N)'	System	01 Aug 2020 02:43:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:43:48', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e587bb65-f594-4baa-a611-37cc01555281'	System	01 Aug 2020 02:43:52
User entered '31 Jul 2020 22:43'	System	01 Aug 2020 02:43:52

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 21:05'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 2'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:33:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8f96ef08-76a6-4849-8e96-22d69badf5c0'	System	02 Aug 2020 01:33:58
User entered 'Yes (Y)'	System	02 Aug 2020 01:33:58

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:33:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8f96ef08-76a6-4849-8e96-22d69badf5c0'	System	02 Aug 2020 01:33:58
User entered '97.7'	System	02 Aug 2020 01:33:58

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:33:46', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8f96ef08-76a6-4849-8e96-22d69badf5c0'	System	02 Aug 2020 01:33:58
User entered 'No (N)'	System	02 Aug 2020 01:33:58

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:33:54', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8f96ef08-76a6-4849-8e96-22d69badf5c0'	System	02 Aug 2020 01:33:58
User entered '01 Aug 2020 21:33'	System	02 Aug 2020 01:33:58

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 3'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0e20b74e-3cc4-40b8-89d1-ed92225f3e2a'	System	03 Aug 2020 02:07:25
User entered 'Yes (Y)'	System	03 Aug 2020 02:07:25



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0e20b74e-3cc4-40b8-89d1-ed92225f3e2a'	System	03 Aug 2020 02:07:25
User entered '97.9'	System	03 Aug 2020 02:07:25

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:17', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0e20b74e-3cc4-40b8-89d1-ed92225f3e2a'	System	03 Aug 2020 02:07:25
User entered 'No (N)'	System	03 Aug 2020 02:07:25

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0e20b74e-3cc4-40b8-89d1-ed92225f3e2a'	System	03 Aug 2020 02:07:25
User entered '02 Aug 2020 22:07'	System	03 Aug 2020 02:07:25

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 4'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a7280a31-297d-41aa-81ea-d6322077c845'	System	04 Aug 2020 01:17:27
User entered 'Yes (Y)'	System	04 Aug 2020 01:17:27

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a7280a31-297d-41aa-81ea-d6322077c845'	System	04 Aug 2020 01:17:27
User entered '98.4'	System	04 Aug 2020 01:17:27



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:17', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a7280a31-297d-41aa-81ea-d6322077c845'	System	04 Aug 2020 01:17:27
User entered 'No (N)'	System	04 Aug 2020 01:17:27

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a7280a31-297d-41aa-81ea-d6322077c845'	System	04 Aug 2020 01:17:27
User entered '03 Aug 2020 21:17'	System	04 Aug 2020 01:17:27

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 5'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:13', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '983c52da-ea8a-4840-81bd-955626600223'	System	05 Aug 2020 01:32:33
User entered 'Yes (Y)'	System	05 Aug 2020 01:32:33

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '983c52da-ea8a-4840-81bd-955626600223'	System	05 Aug 2020 01:32:33
User entered '97.4'	System	05 Aug 2020 01:32:33

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '983c52da-ea8a-4840-81bd-955626600223'	System	05 Aug 2020 01:32:33
User entered 'No (N)'	System	05 Aug 2020 01:32:33



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '983c52da-ea8a-4840-81bd-955626600223'	System	05 Aug 2020 01:32:33
User entered '04 Aug 2020 21:32'	System	05 Aug 2020 01:32:33

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 6'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd3a5e0bd-817b-4b29-a8b9-9371d3d8d54f'	System	06 Aug 2020 01:01:45
User entered 'Yes (Y)'	System	06 Aug 2020 01:01:45

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd3a5e0bd-817b-4b29-a8b9-9371d3d8d54f'	System	06 Aug 2020 01:01:45
User entered '98.0'	System	06 Aug 2020 01:01:45

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:36', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd3a5e0bd-817b-4b29-a8b9-9371d3d8d54f'	System	06 Aug 2020 01:01:45
User entered 'No (N)'	System	06 Aug 2020 01:01:45

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:41', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd3a5e0bd-817b-4b29-a8b9-9371d3d8d54f'	System	06 Aug 2020 01:01:45
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 01:01:45



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 7'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:19:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd42345db-0d70-4855-bf5d-0ee4e91d1c37'	System	07 Aug 2020 01:20:11
User entered 'Yes (Y)'	System	07 Aug 2020 01:20:11

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:19:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd42345db-0d70-4855-bf5d-0ee4e91d1c37'	System	07 Aug 2020 01:20:11
User entered '97.3'	System	07 Aug 2020 01:20:11

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:05', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd42345db-0d70-4855-bf5d-0ee4e91d1c37'	System	07 Aug 2020 01:20:11
User entered 'No (N)'	System	07 Aug 2020 01:20:11

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:08', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd42345db-0d70-4855-bf5d-0ee4e91d1c37'	System	07 Aug 2020 01:20:11
User entered '06 Aug 2020 21:20'	System	07 Aug 2020 01:20:11

US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:12:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dbf7582c-f5eb-4555-9d24-095cd87435d3'	System	31 Jul 2020 23:13:13
User entered 'None (1)'	System	31 Jul 2020 23:13:13

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:12:48', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dbf7582c-f5eb-4555-9d24-095cd87435d3'	System	31 Jul 2020 23:13:13
User entered 'No (N)'	System	31 Jul 2020 23:13:13

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:12:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dbf7582c-f5eb-4555-9d24-095cd87435d3'	System	31 Jul 2020 23:13:13
User entered 'No (N)'	System	31 Jul 2020 23:13:13

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dbf7582c-f5eb-4555-9d24-095cd87435d3'	System	31 Jul 2020 23:13:13
User entered 'None (1)'	System	31 Jul 2020 23:13:13

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dbf7582c-f5eb-4555-9d24-095cd87435d3'	System	31 Jul 2020 23:13:13
User entered '31 Jul 2020 19:13'	System	31 Jul 2020 23:13:13

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 17:40'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 20:10'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '264b3bbf-45d6-4f9f-8b5f-c68b04c4b3fd'	System	01 Aug 2020 02:44:27
User entered 'None (1)'	System	01 Aug 2020 02:44:27

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:07', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '264b3bbf-45d6-4f9f-8b5f-c68b04c4b3fd'	System	01 Aug 2020 02:44:27
User entered 'No (N)'	System	01 Aug 2020 02:44:27

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '264b3bbf-45d6-4f9f-8b5f-c68b04c4b3fd'	System	01 Aug 2020 02:44:27
User entered 'No (N)'	System	01 Aug 2020 02:44:27

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:19', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '264b3bbf-45d6-4f9f-8b5f-c68b04c4b3fd'	System	01 Aug 2020 02:44:27
User entered 'None (1)'	System	01 Aug 2020 02:44:27

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '264b3bbf-45d6-4f9f-8b5f-c68b04c4b3fd'	System	01 Aug 2020 02:44:27
User entered '31 Jul 2020 22:44'	System	01 Aug 2020 02:44:27

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 21:05'	System	31 Jul 2020 21:32:56



**US3412081**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 2'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:34:11', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e9d9a567-8820-44ba-9cd2-67c5d91e7c50'	System	02 Aug 2020 01:35:07
User entered 'Does not interfere with activity (2)'	System	02 Aug 2020 01:35:07

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:34:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e9d9a567-8820-44ba-9cd2-67c5d91e7c50'	System	02 Aug 2020 01:35:07
User entered 'No (N)'	System	02 Aug 2020 01:35:07

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:34:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e9d9a567-8820-44ba-9cd2-67c5d91e7c50'	System	02 Aug 2020 01:35:07
User entered 'No (N)'	System	02 Aug 2020 01:35:07

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:34:45', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e9d9a567-8820-44ba-9cd2-67c5d91e7c50'	System	02 Aug 2020 01:35:07
User entered 'None (1)'	System	02 Aug 2020 01:35:07

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e9d9a567-8820-44ba-9cd2-67c5d91e7c50'	System	02 Aug 2020 01:35:07
User entered '01 Aug 2020 21:35'	System	02 Aug 2020 01:35:07

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 3'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '13502e80-c5c7-4a03-9fda-1233a8ed8990'	System	03 Aug 2020 02:07:57
User entered 'None (1)'	System	03 Aug 2020 02:07:57

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '13502e80-c5c7-4a03-9fda-1233a8ed8990'	System	03 Aug 2020 02:07:57
User entered 'No (N)'	System	03 Aug 2020 02:07:57

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '13502e80-c5c7-4a03-9fda-1233a8ed8990'	System	03 Aug 2020 02:07:57
User entered 'No (N)'	System	03 Aug 2020 02:07:57

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:50', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '13502e80-c5c7-4a03-9fda-1233a8ed8990'	System	03 Aug 2020 02:07:57
User entered 'None (1)'	System	03 Aug 2020 02:07:57

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:07:55', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '13502e80-c5c7-4a03-9fda-1233a8ed8990'	System	03 Aug 2020 02:07:57
User entered '02 Aug 2020 22:07'	System	03 Aug 2020 02:07:57

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 4'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:29', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '71eaf314-3b8c-4821-b72d-b43e52d0ab20'	System	04 Aug 2020 01:17:55
User entered 'None (1)'	System	04 Aug 2020 01:17:55

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:34', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '71eaf314-3b8c-4821-b72d-b43e52d0ab20'	System	04 Aug 2020 01:17:55
User entered 'No (N)'	System	04 Aug 2020 01:17:55

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:39', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '71eaf314-3b8c-4821-b72d-b43e52d0ab20'	System	04 Aug 2020 01:17:55
User entered 'No (N)'	System	04 Aug 2020 01:17:55

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '71eaf314-3b8c-4821-b72d-b43e52d0ab20'	System	04 Aug 2020 01:17:55
User entered 'None (1)'	System	04 Aug 2020 01:17:55

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:17:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '71eaf314-3b8c-4821-b72d-b43e52d0ab20'	System	04 Aug 2020 01:17:55
User entered '03 Aug 2020 21:17'	System	04 Aug 2020 01:17:55

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 5'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:36', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc669253-5ea9-449a-baac-bc708215129e'	System	05 Aug 2020 01:32:56
User entered 'None (1)'	System	05 Aug 2020 01:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc669253-5ea9-449a-baac-bc708215129e'	System	05 Aug 2020 01:32:56
User entered 'No (N)'	System	05 Aug 2020 01:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc669253-5ea9-449a-baac-bc708215129e'	System	05 Aug 2020 01:32:56
User entered 'No (N)'	System	05 Aug 2020 01:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:47', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc669253-5ea9-449a-baac-bc708215129e'	System	05 Aug 2020 01:32:56
User entered 'None (1)'	System	05 Aug 2020 01:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc669253-5ea9-449a-baac-bc708215129e'	System	05 Aug 2020 01:32:56
User entered '04 Aug 2020 21:32'	System	05 Aug 2020 01:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 6'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:46', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '88195798-074d-4bad-aef2-18b58f55eb18'	System	06 Aug 2020 01:02:08
User entered 'None (1)'	System	06 Aug 2020 01:02:08

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '88195798-074d-4bad-aef2-18b58f55eb18'	System	06 Aug 2020 01:02:08
User entered 'No (N)'	System	06 Aug 2020 01:02:08

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:55', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '88195798-074d-4bad-aef2-18b58f55eb18'	System	06 Aug 2020 01:02:08
User entered 'No (N)'	System	06 Aug 2020 01:02:08

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:01:58', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '88195798-074d-4bad-aef2-18b58f55eb18'	System	06 Aug 2020 01:02:08
User entered 'None (1)'	System	06 Aug 2020 01:02:08

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '88195798-074d-4bad-aef2-18b58f55eb18'	System	06 Aug 2020 01:02:08
User entered '05 Aug 2020 21:02'	System	06 Aug 2020 01:02:08

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



**US3412081**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 7'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6e12e557-55cf-4338-838d-a1d1aad4d37e'	System	07 Aug 2020 01:20:35
User entered 'None (1)'	System	07 Aug 2020 01:20:35

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6e12e557-55cf-4338-838d-a1d1aad4d37e'	System	07 Aug 2020 01:20:35
User entered 'No (N)'	System	07 Aug 2020 01:20:35

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6e12e557-55cf-4338-838d-a1d1aad4d37e'	System	07 Aug 2020 01:20:35
User entered 'No (N)'	System	07 Aug 2020 01:20:35

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:27', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6e12e557-55cf-4338-838d-a1d1aad4d37e'	System	07 Aug 2020 01:20:35
User entered 'None (1)'	System	07 Aug 2020 01:20:35

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '6e12e557-55cf-4338-838d-a1d1aad4d37e'	System	07 Aug 2020 01:20:35
User entered '06 Aug 2020 21:20'	System	07 Aug 2020 01:20:35

US3412081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



**US3412081**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:29', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:38', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'None (0)'	System	31 Jul 2020 23:13:51



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered 'No (N)'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T19:13:46', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '452f5799-d949-4e72-b6fb-4fce2f5ff4b7'	System	31 Jul 2020 23:13:51
User entered '31 Jul 2020 19:13'	System	31 Jul 2020 23:13:51

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 17:40'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 20:10'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:54', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:44:58', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:07', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'None (0)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered 'No (N)'	System	01 Aug 2020 02:45:44

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-07-31T22:45:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'e4eba435-e798-43d2-9b50-e43089277813'	System	01 Aug 2020 02:45:44
User entered '31 Jul 2020 22:45'	System	01 Aug 2020 02:45:44

**US3412081**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Jul 2020 21:05'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 2'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'None (0)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'No interference with activity (1)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:28', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'None (0)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'None (0)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:41', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'None (0)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'None (0)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:35:56', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered 'No (N)'	System	02 Aug 2020 01:36:04

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-01T21:36:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25cb9a69-f82b-406d-b356-5bdda32d5a9b'	System	02 Aug 2020 01:36:04
User entered '01 Aug 2020 21:36'	System	02 Aug 2020 01:36:04



**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 3'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:08', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:11', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'None (0)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered 'No (N)'	System	03 Aug 2020 02:08:32

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-02T22:08:27', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7805647a-8790-440c-8fe3-05df3865d1c4'	System	03 Aug 2020 02:08:32
User entered '02 Aug 2020 22:08'	System	03 Aug 2020 02:08:32

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 4'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:13', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:16', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'None (0)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:20', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered 'No (N)'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-03T21:18:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fe743861-e055-43b2-8f81-f99209dedd43'	System	04 Aug 2020 01:18:28
User entered '03 Aug 2020 21:18'	System	04 Aug 2020 01:18:28

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:32:56



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 5'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:32:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:02', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'None (0)'	System	05 Aug 2020 01:33:21

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:15', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered 'No (N)'	System	05 Aug 2020 01:33:21



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-04T21:33:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '84833331-e3c9-4ccc-bfa8-b53578b3b55d'	System	05 Aug 2020 01:33:21
User entered '04 Aug 2020 21:33'	System	05 Aug 2020 01:33:21

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 6'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:11', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'None (0)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'Some interference with activity (2)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'None (0)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'None (0)'	System	06 Aug 2020 01:02:50



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'None (0)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'None (0)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered 'No (N)'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-05T21:02:48', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b61ac632-a48e-4fb1-83be-8816513a5ba5'	System	06 Aug 2020 01:02:50
User entered '05 Aug 2020 21:02'	System	06 Aug 2020 01:02:50

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 7'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:36', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12



US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:39', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:45', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:48', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:20:54', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'None (0)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:21:05', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered 'No (N)'	System	07 Aug 2020 01:21:12

US3412081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-06T21:21:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4e0a8d33-9442-49f9-9ff1-6ffd65d1768e'	System	07 Aug 2020 01:21:12
User entered '06 Aug 2020 21:21'	System	07 Aug 2020 01:21:12

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 21:32:56



**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	06 Aug 2020 01:02:50
User entered 'Day 8'	System	06 Aug 2020 01:02:50

US3412081

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-07T21:06:34', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9bc61c12-bf7f-4796-b0eb-88760bfd0c52'	System	08 Aug 2020 01:06:43
User entered 'No (N)'	System	08 Aug 2020 01:06:43

US3412081

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-07T21:06:38', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9bc61c12-bf7f-4796-b0eb-88760bfd0c52'	System	08 Aug 2020 01:06:43
User entered '07 Aug 2020 21:06'	System	08 Aug 2020 01:06:43

**US3412081**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:02:50

**US3412081**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:02:50

**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 20:32:47

**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '7 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 20:32:47



**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 20:32:47

**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 20:32:47

**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 20:32:59

**US3412081**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	07 Aug 2020 20:32:59

**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:03

**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:03

**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:03

**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:03



**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:09

**US3412081**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	24 Aug 2020 14:59:09

**US3412081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:26

**US3412081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:26

**US3412081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:26

US3412081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:26

**US3412081**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 14:59:34

**US3412081**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	24 Aug 2020 14:59:34



**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:27:44

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:27:44

US3412081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	System	31 Aug 2020 18:27:53
Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 18:27:53
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).		
User entered empty.	System	31 Aug 2020 18:27:44
	(b) (4), (b) (6)	31 Aug 2020 18:27:44

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'VISIT2'	System	31 Aug 2020 18:27:44

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '14:00'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33



**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Aug 2020 14:00'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '37.0' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	01 Oct 2020 14:43:07
User entered '98.7' F	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '82'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'bpm'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '18'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'breaths/min'	System	17 Sep 2020 19:57:33



US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '142'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '76'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '15:13'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33



US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Aug 2020 15:13'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Sep 2020 19:57:57
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 19:57:57
User entered '97.2' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:57
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 19:57:33
User entered '97.2' C	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '64'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'bpm'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '14'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'breaths/min'	System	17 Sep 2020 19:57:33



US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '124'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '72'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:57:33

US3412081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	17 Sep 2020 19:57:33

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:58:12

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 19:58:12

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:42:41

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:42:41



US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

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)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	31 Aug 2020 18:42:56
User entered '14:40' reason for change: Data Entry Error	System	31 Aug 2020 18:42:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:42:41
User entered '14:' (non-conformant).	System	31 Aug 2020 18:42:41

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Aug 2020 14:40'	System	31 Aug 2020 18:42:56
User entered '31 Aug 2020 14:' (non-conformant).	System	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'ONCE'	System	31 Aug 2020 18:42:41

US3412081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 18:42:41



US3412081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:02:52

US3412081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:02:52

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '14:13'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:02:52

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Aug 2020 14:13'	System	17 Sep 2020 20:02:52

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:30:07**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '31 Aug 2020'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '14:08'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22



**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '31 Aug 2020 14:08'	System	17 Sep 2020 20:03:22

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

US3412081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

US3412081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	Mylene Asmar-Rios (b) (4)	17 Sep 2020 20:03:22

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered empty.	System	17 Sep 2020 20:03:22

US3412081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:48:11

**US3412081**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	08 Sep 2020 14:48:11

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:01:13', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc6b3097-665b-4079-8f81-85eef85d9308'	System	31 Aug 2020 19:02:16
User entered 'Yes (Y)'	System	31 Aug 2020 19:02:16

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:01:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc6b3097-665b-4079-8f81-85eef85d9308'	System	31 Aug 2020 19:02:16
User entered '97.8'	System	31 Aug 2020 19:02:16

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:01:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc6b3097-665b-4079-8f81-85eef85d9308'	System	31 Aug 2020 19:02:16
User entered 'No (N)'	System	31 Aug 2020 19:02:16

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:01:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bc6b3097-665b-4079-8f81-85eef85d9308'	System	31 Aug 2020 19:02:16
User entered '31 Aug 2020 15:01'	System	31 Aug 2020 19:02:16

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 17:30'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:08:13', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2c01b7ec-d712-445c-9b9e-9509eff6e921'	System	01 Sep 2020 01:08:49
User entered 'Yes (Y)'	System	01 Sep 2020 01:08:49



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:08:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2c01b7ec-d712-445c-9b9e-9509eff6e921'	System	01 Sep 2020 01:08:49
User entered '98.2'	System	01 Sep 2020 01:08:49

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:08:29', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2c01b7ec-d712-445c-9b9e-9509eff6e921'	System	01 Sep 2020 01:08:49
User entered 'No (N)'	System	01 Sep 2020 01:08:49

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:08:43', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2c01b7ec-d712-445c-9b9e-9509eff6e921'	System	01 Sep 2020 01:08:49
User entered '31 Aug 2020 21:08'	System	01 Sep 2020 01:08:49

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 2'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:08:43', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ad19fd1a-a446-48ee-b648-2ec5166a6bdc'	System	02 Sep 2020 01:09:10
User entered 'Yes (Y)'	System	02 Sep 2020 01:09:10

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:08:54', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ad19fd1a-a446-48ee-b648-2ec5166a6bdc'	System	02 Sep 2020 01:09:10
User entered '97.7'	System	02 Sep 2020 01:09:10



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:09:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ad19fd1a-a446-48ee-b648-2ec5166a6bdc'	System	02 Sep 2020 01:09:10
User entered 'No (N)'	System	02 Sep 2020 01:09:10

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:09:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ad19fd1a-a446-48ee-b648-2ec5166a6bdc'	System	02 Sep 2020 01:09:10
User entered '01 Sep 2020 21:09'	System	02 Sep 2020 01:09:10

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 3'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:53:45', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd967c91a-769b-4048-9cdb-d37252bbff5b'	System	03 Sep 2020 00:54:07
User entered 'Yes (Y)'	System	03 Sep 2020 00:54:07

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:53:53', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd967c91a-769b-4048-9cdb-d37252bbff5b'	System	03 Sep 2020 00:54:07
User entered '97.9'	System	03 Sep 2020 00:54:07

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:53:56', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd967c91a-769b-4048-9cdb-d37252bbff5b'	System	03 Sep 2020 00:54:07
User entered 'No (N)'	System	03 Sep 2020 00:54:07



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:54:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd967c91a-769b-4048-9cdb-d37252bbff5b'	System	03 Sep 2020 00:54:07
User entered '02 Sep 2020 20:54'	System	03 Sep 2020 00:54:07

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 4'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '635f2fab-0f95-4b45-aa32-7f5088500044'	System	04 Sep 2020 01:23:43
User entered 'Yes (Y)'	System	04 Sep 2020 01:23:43

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '635f2fab-0f95-4b45-aa32-7f5088500044'	System	04 Sep 2020 01:23:43
User entered '98.1'	System	04 Sep 2020 01:23:43

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '635f2fab-0f95-4b45-aa32-7f5088500044'	System	04 Sep 2020 01:23:43
User entered 'No (N)'	System	04 Sep 2020 01:23:43

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '635f2fab-0f95-4b45-aa32-7f5088500044'	System	04 Sep 2020 01:23:43
User entered '03 Sep 2020 21:23'	System	04 Sep 2020 01:23:43



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 5'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:56:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'db74658b-889c-4a0a-a14d-26e2fa58ace3'	System	05 Sep 2020 01:57:14
User entered 'Yes (Y)'	System	05 Sep 2020 01:57:14

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'db74658b-889c-4a0a-a14d-26e2fa58ace3'	System	05 Sep 2020 01:57:14
User entered '97.7'	System	05 Sep 2020 01:57:14

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:07', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'db74658b-889c-4a0a-a14d-26e2fa58ace3'	System	05 Sep 2020 01:57:14
User entered 'No (N)'	System	05 Sep 2020 01:57:14

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'db74658b-889c-4a0a-a14d-26e2fa58ace3'	System	05 Sep 2020 01:57:14
User entered '04 Sep 2020 21:57'	System	05 Sep 2020 01:57:14

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 6'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7dec47b8-f56f-472b-b97b-87569a3a031e'	System	06 Sep 2020 01:37:46
User entered 'Yes (Y)'	System	06 Sep 2020 01:37:46

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7dec47b8-f56f-472b-b97b-87569a3a031e'	System	06 Sep 2020 01:37:46
User entered '96.4'	System	06 Sep 2020 01:37:46

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7dec47b8-f56f-472b-b97b-87569a3a031e'	System	06 Sep 2020 01:37:46
User entered 'No (N)'	System	06 Sep 2020 01:37:46

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:43', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '7dec47b8-f56f-472b-b97b-87569a3a031e'	System	06 Sep 2020 01:37:46
User entered '05 Sep 2020 21:37'	System	06 Sep 2020 01:37:46

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 7'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:02', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5363552e-c7b4-4b16-87df-50d024e40717'	System	07 Sep 2020 02:18:19
User entered 'Yes (Y)'	System	07 Sep 2020 02:18:19

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5363552e-c7b4-4b16-87df-50d024e40717'	System	07 Sep 2020 02:18:19
User entered '97.0'	System	07 Sep 2020 02:18:19

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5363552e-c7b4-4b16-87df-50d024e40717'	System	07 Sep 2020 02:18:19
User entered 'No (N)'	System	07 Sep 2020 02:18:19

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5363552e-c7b4-4b16-87df-50d024e40717'	System	07 Sep 2020 02:18:19
User entered '06 Sep 2020 22:18'	System	07 Sep 2020 02:18:19

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:02:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'edee5513-e724-4feb-a1b7-38fdc2e0a3f5'	System	01 Sep 2020 01:08:06
User entered 'None (1)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:02:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'edee5513-e724-4feb-a1b7-38fdc2e0a3f5'	System	01 Sep 2020 01:08:06
User entered 'No (N)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:02:38', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'edee5513-e724-4feb-a1b7-38fdc2e0a3f5'	System	01 Sep 2020 01:08:06
User entered 'No (N)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:02:57', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'edee5513-e724-4feb-a1b7-38fdc2e0a3f5'	System	01 Sep 2020 01:08:06
User entered 'None (1)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'edee5513-e724-4feb-a1b7-38fdc2e0a3f5'	System	01 Sep 2020 01:08:06
User entered '31 Aug 2020 15:03'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 17:30'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:08:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '967398c9-1e10-4691-9ab0-115963b60ece'	System	01 Sep 2020 01:10:29
User entered 'None (1)'	System	01 Sep 2020 01:10:29

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '967398c9-1e10-4691-9ab0-115963b60ece'	System	01 Sep 2020 01:10:29
User entered 'No (N)'	System	01 Sep 2020 01:10:29

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '967398c9-1e10-4691-9ab0-115963b60ece'	System	01 Sep 2020 01:10:29
User entered 'No (N)'	System	01 Sep 2020 01:10:29

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:19', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '967398c9-1e10-4691-9ab0-115963b60ece'	System	01 Sep 2020 01:10:29
User entered 'None (1)'	System	01 Sep 2020 01:10:29

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '967398c9-1e10-4691-9ab0-115963b60ece'	System	01 Sep 2020 01:10:29
User entered '31 Aug 2020 21:10'	System	01 Sep 2020 01:10:29

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 2'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:09:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '858db6c0-89b4-472a-8102-8f6257808960'	System	02 Sep 2020 01:15:23
User entered 'None (1)'	System	02 Sep 2020 01:15:23

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '858db6c0-89b4-472a-8102-8f6257808960'	System	02 Sep 2020 01:15:23
User entered 'No (N)'	System	02 Sep 2020 01:15:23

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '858db6c0-89b4-472a-8102-8f6257808960'	System	02 Sep 2020 01:15:23
User entered 'No (N)'	System	02 Sep 2020 01:15:23

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '858db6c0-89b4-472a-8102-8f6257808960'	System	02 Sep 2020 01:15:23
User entered 'None (1)'	System	02 Sep 2020 01:15:23

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:20', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '858db6c0-89b4-472a-8102-8f6257808960'	System	02 Sep 2020 01:15:23
User entered '01 Sep 2020 21:15'	System	02 Sep 2020 01:15:23

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 3'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:54:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8a2cac93-04a2-4591-960f-5655a7908f69'	System	03 Sep 2020 00:55:26
User entered 'None (1)'	System	03 Sep 2020 00:55:26

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:54:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8a2cac93-04a2-4591-960f-5655a7908f69'	System	03 Sep 2020 00:55:26
User entered 'No (N)'	System	03 Sep 2020 00:55:26

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8a2cac93-04a2-4591-960f-5655a7908f69'	System	03 Sep 2020 00:55:26
User entered 'No (N)'	System	03 Sep 2020 00:55:26

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8a2cac93-04a2-4591-960f-5655a7908f69'	System	03 Sep 2020 00:55:26
User entered 'None (1)'	System	03 Sep 2020 00:55:26

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8a2cac93-04a2-4591-960f-5655a7908f69'	System	03 Sep 2020 00:55:26
User entered '02 Sep 2020 20:55'	System	03 Sep 2020 00:55:26

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 4'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:56', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9c6c7a42-f516-470c-b221-6e4de87046d6'	System	04 Sep 2020 01:24:16
User entered 'None (1)'	System	04 Sep 2020 01:24:16

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:23:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9c6c7a42-f516-470c-b221-6e4de87046d6'	System	04 Sep 2020 01:24:16
User entered 'No (N)'	System	04 Sep 2020 01:24:16

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9c6c7a42-f516-470c-b221-6e4de87046d6'	System	04 Sep 2020 01:24:16
User entered 'No (N)'	System	04 Sep 2020 01:24:16

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:08', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9c6c7a42-f516-470c-b221-6e4de87046d6'	System	04 Sep 2020 01:24:16
User entered 'None (1)'	System	04 Sep 2020 01:24:16

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:12', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9c6c7a42-f516-470c-b221-6e4de87046d6'	System	04 Sep 2020 01:24:16
User entered '03 Sep 2020 21:24'	System	04 Sep 2020 01:24:16

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 5'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:17', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '31bb667d-d0ad-4bd5-a756-b0e4522d147a'	System	05 Sep 2020 01:57:48
User entered 'None (1)'	System	05 Sep 2020 01:57:48

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '31bb667d-d0ad-4bd5-a756-b0e4522d147a'	System	05 Sep 2020 01:57:48
User entered 'No (N)'	System	05 Sep 2020 01:57:48

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '31bb667d-d0ad-4bd5-a756-b0e4522d147a'	System	05 Sep 2020 01:57:48
User entered 'No (N)'	System	05 Sep 2020 01:57:48

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '31bb667d-d0ad-4bd5-a756-b0e4522d147a'	System	05 Sep 2020 01:57:48
User entered 'None (1)'	System	05 Sep 2020 01:57:48

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:46', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '31bb667d-d0ad-4bd5-a756-b0e4522d147a'	System	05 Sep 2020 01:57:48
User entered '04 Sep 2020 21:57'	System	05 Sep 2020 01:57:48

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 6'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1c450d2b-55de-4b52-b776-c542fb0e1cdb'	System	06 Sep 2020 01:38:10
User entered 'None (1)'	System	06 Sep 2020 01:38:10

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:54', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1c450d2b-55de-4b52-b776-c542fb0e1cdb'	System	06 Sep 2020 01:38:10
User entered 'No (N)'	System	06 Sep 2020 01:38:10

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:37:58', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1c450d2b-55de-4b52-b776-c542fb0e1cdb'	System	06 Sep 2020 01:38:10
User entered 'No (N)'	System	06 Sep 2020 01:38:10

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1c450d2b-55de-4b52-b776-c542fb0e1cdb'	System	06 Sep 2020 01:38:10
User entered 'None (1)'	System	06 Sep 2020 01:38:10

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1c450d2b-55de-4b52-b776-c542fb0e1cdb'	System	06 Sep 2020 01:38:10
User entered '05 Sep 2020 21:38'	System	06 Sep 2020 01:38:10

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 7'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fb215659-a0f0-4d64-bf8e-05ba46cfaf20'	System	07 Sep 2020 02:18:40
User entered 'None (1)'	System	07 Sep 2020 02:18:40

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:28', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fb215659-a0f0-4d64-bf8e-05ba46cfaf20'	System	07 Sep 2020 02:18:40
User entered 'No (N)'	System	07 Sep 2020 02:18:40

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fb215659-a0f0-4d64-bf8e-05ba46cfaf20'	System	07 Sep 2020 02:18:40
User entered 'No (N)'	System	07 Sep 2020 02:18:40

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:34', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fb215659-a0f0-4d64-bf8e-05ba46cfaf20'	System	07 Sep 2020 02:18:40
User entered 'None (1)'	System	07 Sep 2020 02:18:40

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:38', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fb215659-a0f0-4d64-bf8e-05ba46cfaf20'	System	07 Sep 2020 02:18:40
User entered '06 Sep 2020 22:18'	System	07 Sep 2020 02:18:40

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:22', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'None (0)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:43', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered 'No (N)'	System	01 Sep 2020 01:08:06

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T15:03:50', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '25b53497-2b0d-459a-9914-a10decdd69aa'	System	01 Sep 2020 01:08:06
User entered '31 Aug 2020 15:03'	System	01 Sep 2020 01:08:06



**US3412081**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 18:42:56

**US3412081**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 17:30'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:39', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:45', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'None (0)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:10:56', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered 'No (N)'	System	01 Sep 2020 01:11:03

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-08-31T21:11:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fc6a7cbf-336d-47f8-a37c-a1d04d580c00'	System	01 Sep 2020 01:11:03
User entered '31 Aug 2020 21:11'	System	01 Sep 2020 01:11:03

**US3412081**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 18:42:56

**US3412081**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:30:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 2'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:27', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:34', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'None (0)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered 'No (N)'	System	02 Sep 2020 01:16:02

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-01T21:15:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '2003ebec-4092-44cf-861b-763b3eb4ff4f'	System	02 Sep 2020 01:16:02
User entered '01 Sep 2020 21:15'	System	02 Sep 2020 01:16:02

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 3'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:40', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:43', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'None (0)'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:47', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered 'No (N)'	System	03 Sep 2020 00:55:53



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-02T20:55:50', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '093e8c88-29cc-4112-b37a-1d9b56940c13'	System	03 Sep 2020 00:55:53
User entered '02 Sep 2020 20:55'	System	03 Sep 2020 00:55:53

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 4'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:23', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:29', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'None (0)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:45', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered 'No (N)'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-03T21:24:50', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ce880e01-baa7-4ccb-9243-0425f1e1c884'	System	04 Sep 2020 01:24:55
User entered '03 Sep 2020 21:24'	System	04 Sep 2020 01:24:55

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 5'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:53', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:56', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:57:59', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:58:02', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:58:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'None (0)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:58:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered 'No (N)'	System	05 Sep 2020 01:58:16

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-04T21:58:13', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'dce4667c-aed2-49a3-b441-40cbcd75cbb5'	System	05 Sep 2020 01:58:16
User entered '04 Sep 2020 21:58'	System	05 Sep 2020 01:58:16

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:42:56



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 6'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:19', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:24', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:27', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:30', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'None (0)'	System	06 Sep 2020 01:38:41



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered 'No (N)'	System	06 Sep 2020 01:38:41

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-05T21:38:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '0b6aeb63-eb18-4bac-98c3-9a81f8fe6ac1'	System	06 Sep 2020 01:38:41
User entered '05 Sep 2020 21:38'	System	06 Sep 2020 01:38:41

**US3412081**

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

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

**Generated On: 09 Jun 2021 17:30:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Aug 2020 18:42:56
User entered 'Day 7'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:46', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04



US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:53', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'None (0)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:18:57', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered 'No (N)'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1ff4387d86e1131f)', Time: '2020-09-06T22:19:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '67564b93-22f5-46e0-86a1-1451a91fcc22'	System	07 Sep 2020 02:19:04
User entered '06 Sep 2020 22:19'	System	07 Sep 2020 02:19:04

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:42:56

US3412081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:30:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:42:56

**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:58:53



**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:58:53

**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:58:53

**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:58:53

**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 14:58:58

**US3412081**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	08 Sep 2020 14:58:58

**US3412081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:42:47

**US3412081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:01
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:42:47

**US3412081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:42:47



**US3412081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:01
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:42:47

US3412081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:42:52

**US3412081**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	14 Sep 2020 13:42:52

**US3412081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Sep 2020 14:35:46

**US3412081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '21 Sep 2020'	Mason Urban (b) (4)	21 Sep 2020 14:35:46

US3412081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Sep 2020 14:35:46

**US3412081**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	Mason Urban (b) (4)	21 Sep 2020 14:35:46

**US3412081**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Sep 2020 14:36:00



**US3412081**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	21 Sep 2020 14:36:00

US3412081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 18:20:14

**US3412081**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 18:20:14

US3412081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	28 Sep 2020 18:20:14

**US3412081**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'VISIT3'	System	28 Sep 2020 18:20:14

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '13:25'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03



**US3412081**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '28 Sep 2020 13:25'	System	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '36.7' C	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

**US3412081**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty.	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

**US3412081**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '58'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

**US3412081**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'bpm'	System	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '16'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'breaths/min'	System	28 Sep 2020 18:21:03



US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '124'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '80'	Steven Anderson (b) (4)	28 Sep 2020 18:21:03

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'mmHg'	System	28 Sep 2020 18:21:03

**US3412081**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01

US3412081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01

US3412081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	21 Oct 2020 14:00:19
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 18:21:14

US3412081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	21 Oct 2020 14:00:19
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 18:21:14



US3412081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 18:21:30

US3412081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '28 Sep 2020'	Steven Anderson (b) (4)	28 Sep 2020 18:21:30

**US3412081**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered '13:30' reason for change: Data Entry Error	Melissa Fuson (b) (4)	01 Oct 2020 14:49:13
User entered '13:25'	Steven Anderson (b) (4)	28 Sep 2020 18:21:30

**US3412081**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered '28 Sep 2020 13:30'	System	01 Oct 2020 14:49:13
User entered '28 Sep 2020 13:25'	System	28 Sep 2020 18:21:30

US3412081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:33:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Sep 2020 18:21:35

**US3412081**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	28 Sep 2020 18:21:35

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 64'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-09-30T15:16:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '47e8eed4-8585-4d1f-9a8c-1ea415118f57'	System	30 Sep 2020 19:16:38
User entered 'No (N)'	System	30 Sep 2020 19:16:38



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-09-30T15:16:27', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '47e8eed4-8585-4d1f-9a8c-1ea415118f57'	System	30 Sep 2020 19:16:38
User entered 'No (N)'	System	30 Sep 2020 19:16:38

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-09-30T15:16:36', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '47e8eed4-8585-4d1f-9a8c-1ea415118f57'	System	30 Sep 2020 19:16:38
User entered '30 Sep 2020 15:16:36'	System	30 Sep 2020 19:16:38

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 71'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-07T19:34:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1b415db1-9bad-47ac-8957-3c4cd9f0bc8e'	System	07 Oct 2020 23:34:58
User entered 'No (N)'	System	07 Oct 2020 23:34:58

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-07T19:34:47', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1b415db1-9bad-47ac-8957-3c4cd9f0bc8e'	System	07 Oct 2020 23:34:58
User entered 'No (N)'	System	07 Oct 2020 23:34:58

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-07T19:34:53', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1b415db1-9bad-47ac-8957-3c4cd9f0bc8e'	System	07 Oct 2020 23:34:58
User entered '07 Oct 2020 19:34:53'	System	07 Oct 2020 23:34:58



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 21:32:56

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 78'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-14T11:55:51', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '03e274f7-1d48-49d6-a354-2ca43113a15d'	System	14 Oct 2020 15:56:09
User entered 'No (N)'	System	14 Oct 2020 15:56:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-14T11:56:02', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '03e274f7-1d48-49d6-a354-2ca43113a15d'	System	14 Oct 2020 15:56:09
User entered 'No (N)'	System	14 Oct 2020 15:56:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-14T11:56:07', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '03e274f7-1d48-49d6-a354-2ca43113a15d'	System	14 Oct 2020 15:56:09
User entered '14 Oct 2020 11:56:07'	System	14 Oct 2020 15:56:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 21:32:56



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 92'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-28T20:58:57', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd480af04-181b-4197-bc2d-5817cfa0cc91'	System	29 Oct 2020 00:59:07
User entered 'No (N)'	System	29 Oct 2020 00:59:07

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-28T20:59:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd480af04-181b-4197-bc2d-5817cfa0cc91'	System	29 Oct 2020 00:59:07
User entered 'No (N)'	System	29 Oct 2020 00:59:07

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-10-28T20:59:06', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'd480af04-181b-4197-bc2d-5817cfa0cc91'	System	29 Oct 2020 00:59:07
User entered '28 Oct 2020 20:59:06'	System	29 Oct 2020 00:59:07

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 99'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-04T21:37:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1d034646-fc9f-4c18-8f12-9ee70879dea7'	System	05 Nov 2020 02:37:14
User entered 'No (N)'	System	05 Nov 2020 02:37:14



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-04T21:37:05', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1d034646-fc9f-4c18-8f12-9ee70879dea7'	System	05 Nov 2020 02:37:14
User entered 'No (N)'	System	05 Nov 2020 02:37:14

US3412081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-04T21:37:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1d034646-fc9f-4c18-8f12-9ee70879dea7'	System	05 Nov 2020 02:37:14
User entered '04 Nov 2020 21:37:09'	System	05 Nov 2020 02:37:14

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 106'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-11T07:10:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bbe6b928-9159-4397-b680-4f5f4a7de50d'	System	11 Nov 2020 12:10:38
User entered 'No (N)'	System	11 Nov 2020 12:10:38

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-11T07:10:31', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bbe6b928-9159-4397-b680-4f5f4a7de50d'	System	11 Nov 2020 12:10:38
User entered 'No (N)'	System	11 Nov 2020 12:10:38

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-11T07:10:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bbe6b928-9159-4397-b680-4f5f4a7de50d'	System	11 Nov 2020 12:10:38
User entered '11 Nov 2020 07:10:35'	System	11 Nov 2020 12:10:38



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:52:08
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09
Data entry locked.	System	31 Jul 2020 21:32:56
User entered 'Day 113'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:08:09
Data entry locked.	System	31 Jul 2020 21:32:56
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 21:32:56

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2020-11-25T01:27:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered 'Yes (Y)'	System	25 Nov 2020 06:28:44



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2020-11-25T01:27:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered 'No (N)'	System	25 Nov 2020 06:28:44

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-25T01:28:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered 'No (N)'	System	25 Nov 2020 06:28:44

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-25T01:28:09', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered 'Yes (Y)'	System	25 Nov 2020 06:28:44

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please 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 (4cb68b63916968d0)', Time: '2020-11-25T01:28:25', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 06:28:44

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-25T01:28:35', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '4dd10029-6897-40ba-bfc2-92c0f41cf68f'	System	25 Nov 2020 06:28:44
User entered '25 Nov 2020 01:28:35'	System	25 Nov 2020 06:28:44

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:08:09



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2020-11-29T16:56:15', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1dba80e0-e229-4e04-b21b-da1a338f2cd8'	System	29 Nov 2020 21:56:27
User entered 'No (N)'	System	29 Nov 2020 21:56:27

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2020-11-29T16:56:20', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1dba80e0-e229-4e04-b21b-da1a338f2cd8'	System	29 Nov 2020 21:56:27
User entered 'No (N)'	System	29 Nov 2020 21:56:27

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-11-29T16:56:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '1dba80e0-e229-4e04-b21b-da1a338f2cd8'	System	29 Nov 2020 21:56:27
User entered '29 Nov 2020 16:56:26'	System	29 Nov 2020 21:56:27

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2020-12-08T17:12:03', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '21f22830-acb3-46a1-b044-98f12ee4217c'	System	08 Dec 2020 22:12:18
User entered 'No (N)'	System	08 Dec 2020 22:12:18

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2020-12-08T17:12:10', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '21f22830-acb3-46a1-b044-98f12ee4217c'	System	08 Dec 2020 22:12:18
User entered 'No (N)'	System	08 Dec 2020 22:12:18



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-12-08T17:12:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '21f22830-acb3-46a1-b044-98f12ee4217c'	System	08 Dec 2020 22:12:18
User entered '08 Dec 2020 17:12:14'	System	08 Dec 2020 22:12:18

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2020-12-15T14:33:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '63be9c93-c501-4592-ab85-c3d4330cf61e'	System	15 Dec 2020 19:33:51
User entered 'No (N)'	System	15 Dec 2020 19:33:51

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2020-12-15T14:33:42', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '63be9c93-c501-4592-ab85-c3d4330cf61e'	System	15 Dec 2020 19:33:51
User entered 'No (N)'	System	15 Dec 2020 19:33:51

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-12-15T14:33:48', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '63be9c93-c501-4592-ab85-c3d4330cf61e' User entered '15 Dec 2020 14:33:48'	System	15 Dec 2020 19:33:51
	System	15 Dec 2020 19:33:51

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2020-12-28T18:12:14', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a4bb83df-73a6-4810-8642-1e8f63645a3b'	System	28 Dec 2020 23:12:24
User entered 'No (N)'	System	28 Dec 2020 23:12:24

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2020-12-28T18:12:18', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a4bb83df-73a6-4810-8642-1e8f63645a3b'	System	28 Dec 2020 23:12:24
User entered 'No (N)'	System	28 Dec 2020 23:12:24

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2020-12-28T18:12:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'a4bb83df-73a6-4810-8642-1e8f63645a3b'	System	28 Dec 2020 23:12:24
User entered '28 Dec 2020 18:12:21'	System	28 Dec 2020 23:12:24



**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-01-03T10:11:02', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '06a2d943-784d-4456-9bf6-0da9f3b163f9'	System	03 Jan 2021 15:11:15
User entered 'No (N)'	System	03 Jan 2021 15:11:15

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-01-03T10:11:07', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '06a2d943-784d-4456-9bf6-0da9f3b163f9'	System	03 Jan 2021 15:11:15
User entered 'No (N)'	System	03 Jan 2021 15:11:15

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-01-03T10:11:11', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '06a2d943-784d-4456-9bf6-0da9f3b163f9'	System	03 Jan 2021 15:11:15
User entered '03 Jan 2021 10:11:11'	System	03 Jan 2021 15:11:15

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-01-13T07:19:21', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9f1c7dee-bab5-49c0-adf8-5c06fd1ca176'	System	13 Jan 2021 12:19:34
User entered 'No (N)'	System	13 Jan 2021 12:19:34

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-01-13T07:19:26', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9f1c7dee-bab5-49c0-adf8-5c06fd1ca176'	System	13 Jan 2021 12:19:34
User entered 'No (N)'	System	13 Jan 2021 12:19:34

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-01-13T07:19:32', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '9f1c7dee-bab5-49c0-adf8-5c06fd1ca176' User entered '13 Jan 2021 07:19:32'	System	13 Jan 2021 12:19:34
	System	13 Jan 2021 12:19:34

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-01-17T08:40:28', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bcc0c547-8c51-46f2-879e-4977868a03db'	System	17 Jan 2021 13:40:40
User entered 'No (N)'	System	17 Jan 2021 13:40:40



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-01-17T08:40:33', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bcc0c547-8c51-46f2-879e-4977868a03db'	System	17 Jan 2021 13:40:40
User entered 'No (N)'	System	17 Jan 2021 13:40:40

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-01-17T08:40:37', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'bcc0c547-8c51-46f2-879e-4977868a03db' User entered '17 Jan 2021 08:40:37'	System	17 Jan 2021 13:40:40

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-01-26T22:23:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fbc68084-c815-40d6-902e-266b8779bbf1'	System	27 Jan 2021 03:24:05
User entered 'No (N)'	System	27 Jan 2021 03:24:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-01-26T22:23:53', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fbc68084-c815-40d6-902e-266b8779bbf1'	System	27 Jan 2021 03:24:05
User entered 'No (N)'	System	27 Jan 2021 03:24:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-01-26T22:24:01', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'fbc68084-c815-40d6-902e-266b8779bbf1'	System	27 Jan 2021 03:24:05
User entered '26 Jan 2021 22:24:01'	System	27 Jan 2021 03:24:05



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-02-01T07:02:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'be854608-fc30-4951-8b27-4e0597fa9f58'	System	01 Feb 2021 12:02:11
User entered 'No (N)'	System	01 Feb 2021 12:02:11

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-02-01T07:02:04', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'be854608-fc30-4951-8b27-4e0597fa9f58'	System	01 Feb 2021 12:02:11
User entered 'No (N)'	System	01 Feb 2021 12:02:11

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-02-01T07:02:08', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'be854608-fc30-4951-8b27-4e0597fa9f58'	System	01 Feb 2021 12:02:11
User entered '01 Feb 2021 07:02:08'	System	01 Feb 2021 12:02:11

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-02-22T14:34:44', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ae85730a-fede-415b-aeab-1bc3f64c87a0'	System	22 Feb 2021 19:34:59
User entered 'No (N)'	System	22 Feb 2021 19:34:59



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-02-22T14:34:49', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ae85730a-fede-415b-aeab-1bc3f64c87a0'	System	22 Feb 2021 19:34:59
User entered 'No (N)'	System	22 Feb 2021 19:34:59

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-02-22T14:34:52', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'ae85730a-fede-415b-aeab-1bc3f64c87a0'	System	22 Feb 2021 19:34:59
User entered '22 Feb 2021 14:34:52'	System	22 Feb 2021 19:34:59

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-03-01T21:21:47-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'f065c96b-662f-4517-a454-76ea5200cd38'	System	02 Mar 2021 02:29:44
User entered 'No (N)'	System	02 Mar 2021 02:29:44

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-03-01T21:21:50-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'f065c96b-662f-4517-a454-76ea5200cd38'	System	02 Mar 2021 02:29:44
User entered 'No (N)'	System	02 Mar 2021 02:29:44

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-01T21:21:54-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'f065c96b-662f-4517-a454-76ea5200cd38'	System	02 Mar 2021 02:29:44
User entered '01 Mar 2021 21:21:54'	System	02 Mar 2021 02:29:44



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-03-07T00:42:34-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '65c8319e-a685-4570-b164-4cb6d5c61cea' User entered 'No (N)'	System	07 Mar 2021 05:42:50
	System	07 Mar 2021 05:42:50

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-03-07T00:42:40-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '65c8319e-a685-4570-b164-4cb6d5c61cea'	System	07 Mar 2021 05:42:50
User entered 'No (N)'	System	07 Mar 2021 05:42:50

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-07T00:42:44-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '65c8319e-a685-4570-b164-4cb6d5c61cea' User entered '07 Mar 2021 00:42:44'	System	07 Mar 2021 05:42:50
	System	07 Mar 2021 05:42:50

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-03-16T12:30:39-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'c61a8ca2-cfd1-4221-b167-6c82ff61fb66'	System	16 Mar 2021 16:31:00
User entered 'No (N)'	System	16 Mar 2021 16:31:00

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-03-16T12:30:45-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'c61a8ca2-cfd1-4221-b167-6c82ff61fb66'	System	16 Mar 2021 16:31:00
User entered 'No (N)'	System	16 Mar 2021 16:31:00

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-16T12:30:48-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'c61a8ca2-cfd1-4221-b167-6c82ff61fb66'	System	16 Mar 2021 16:31:00
User entered '16 Mar 2021 12:30:48'	System	16 Mar 2021 16:31:00

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-03-25T23:52:56-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b24fb7cd-8d5f-4e35-b745-f3c2ced5974e'	System	26 Mar 2021 03:53:12
User entered 'No (N)'	System	26 Mar 2021 03:53:12



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-03-25T23:53:01-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b24fb7cd-8d5f-4e35-b745-f3c2ced5974e'	System	26 Mar 2021 03:53:12
User entered 'No (N)'	System	26 Mar 2021 03:53:12

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-25T23:53:06-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'b24fb7cd-8d5f-4e35-b745-f3c2ced5974e'	System	26 Mar 2021 03:53:12
User entered '25 Mar 2021 23:53:06'	System	26 Mar 2021 03:53:12

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-03-31T17:26:38-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5287d89e-fa0b-4da4-ad1b-8bf8f5781627'	System	31 Mar 2021 21:26:54
User entered 'No (N)'	System	31 Mar 2021 21:26:54

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-03-31T17:26:41-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5287d89e-fa0b-4da4-ad1b-8bf8f5781627'	System	31 Mar 2021 21:26:54
User entered 'No (N)'	System	31 Mar 2021 21:26:54

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-31T17:26:48-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '5287d89e-fa0b-4da4-ad1b-8bf8f5781627'	System	31 Mar 2021 21:26:54
User entered '31 Mar 2021 17:26:48'	System	31 Mar 2021 21:26:54



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-04-11T15:05:08-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '016a63ff-adeb-49f1-a2f9-53584bb4f336'	System	11 Apr 2021 19:05:19
User entered 'No (N)'	System	11 Apr 2021 19:05:19

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-04-11T15:05:11-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '016a63ff-adeb-49f1-a2f9-53584bb4f336'	System	11 Apr 2021 19:05:19
User entered 'No (N)'	System	11 Apr 2021 19:05:19



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-04-11T15:05:15-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '016a63ff-adeb-49f1-a2f9-53584bb4f336'	System	11 Apr 2021 19:05:19
User entered '11 Apr 2021 15:05:15'	System	11 Apr 2021 19:05:19

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-04-18T22:42:19-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '3478efcf-c24e-4232-b377-25398609306c' User entered 'No (N)'	System	19 Apr 2021 02:42:29
	System	19 Apr 2021 02:42:29

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-04-18T22:42:23-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '3478efcf-c24e-4232-b377-25398609306c'	System	19 Apr 2021 02:42:29
User entered 'No (N)'	System	19 Apr 2021 02:42:29

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-04-18T22:42:26-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '3478efcf-c24e-4232-b377-25398609306c'	System	19 Apr 2021 02:42:29
User entered '18 Apr 2021 22:42:26'	System	19 Apr 2021 02:42:29

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-04-26T10:30:45-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8b9ac141-f08c-44bd-a1ae-60ba53dd999e'	System	26 Apr 2021 14:30:57
User entered 'No (N)'	System	26 Apr 2021 14:30:57

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-04-26T10:30:49-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8b9ac141-f08c-44bd-a1ae-60ba53dd999e'	System	26 Apr 2021 14:30:57
User entered 'No (N)'	System	26 Apr 2021 14:30:57

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-04-26T10:30:53-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '8b9ac141-f08c-44bd-a1ae-60ba53dd999e'	System	26 Apr 2021 14:30:57
User entered '26 Apr 2021 10:30:53'	System	26 Apr 2021 14:30:57

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[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 (4cb68b63916968d0)', Time: '2021-05-03T10:17:13-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered 'Yes (Y)'	System	03 May 2021 14:18:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Have you been exposed to someone with 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 (4cb68b63916968d0)', Time: '2021-05-03T10:17:16-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered 'No (N)'	System	03 May 2021 14:18:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-05-03T10:17:22-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered 'No (N)'	System	03 May 2021 14:18:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-05-03T10:17:31-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered 'Yes (Y)'	System	03 May 2021 14:18:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

Please 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 (4cb68b63916968d0)', Time: '2021-05-03T10:17:39-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 14:18:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-05-03T10:17:54-04:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: '327f9b8d-cb40-44c1-ae53-8cad1d7028a6'	System	03 May 2021 14:18:05
User entered '03 May 2021 10:17:54'	System	03 May 2021 14:18:05

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:08:09



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:08:09



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:08:09



**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:08:09

**US3412081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:30:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:08:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:08:09

US3412081

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:30:07**

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)	26 Apr 2021 07:18:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-01T21:22:03-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'f0fa7406-f855-4c08-a42e-c56347ec4f06'	System	02 Mar 2021 02:29:53
User entered 'No (N)'	System	02 Mar 2021 02:29:53

**US3412081**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4cb68b63916968d0)', Time: '2021-03-01T21:22:07-05:00', User OID: 'PatientReportedOutcome (US3412081)', ODM File OID: 'f0fa7406-f855-4c08-a42e-c56347ec4f06'	System	02 Mar 2021 02:29:53
User entered '01 Mar 2021 21:22:07'	System	02 Mar 2021 02:29:53



**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	26 Oct 2020 16:22:10

**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered '26 Oct 2020'	Mason Urban (b) (4)	26 Oct 2020 16:22:10

**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	26 Oct 2020 16:22:10

**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered empty.	Mason Urban (b) (4)	26 Oct 2020 16:22:10

**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	26 Oct 2020 16:21:58

**US3412081**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:20:01
User entered 'I'	System	26 Oct 2020 16:21:58

**US3412081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:14:19

**US3412081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '2 Dec 2020'	Mason Urban (b) (4)	29 Dec 2020 21:14:19



**US3412081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Dec 2020 21:14:19

**US3412081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	29 Dec 2020 21:14:19

US3412081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:14:27

**US3412081**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User entered 'I'	System	29 Dec 2020 21:14:27

**US3412081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:14:36

**US3412081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '29 Dec 2020'	Mason Urban (b) (4)	29 Dec 2020 21:14:36

**US3412081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Dec 2020 21:14:36

US3412081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	29 Dec 2020 21:14:36



US3412081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:14:41

**US3412081**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User entered 'I'	System	29 Dec 2020 21:14:41

**US3412081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Jan 2021 19:49:03

**US3412081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '28 Jan 2021'	Mason Urban (b) (4)	28 Jan 2021 19:49:03

**US3412081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Jan 2021 19:49:03

**US3412081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	28 Jan 2021 19:49:03

US3412081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Jan 2021 19:48:09

**US3412081**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:01:23
User entered 'I'	System	28 Jan 2021 19:48:09



**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:41:39

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Mylene Asmar-Rios	23 Feb 2021 20:41:39

US3412081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[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 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:41:39

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'VISIT4'	System	23 Feb 2021 20:41:39

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '12:58'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '23 Feb 2021 12:58'	System	30 Mar 2021 13:32:56



US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '97.8' F	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '71'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'bpm'	System	30 Mar 2021 13:32:56

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '16'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'breaths/min'	System	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '130'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56



**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'mmHg'	System	30 Mar 2021 13:32:56

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '70'	Andrea Newlands (b) (4)	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'mmHg'	System	30 Mar 2021 13:32:56

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46

US3412081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46

US3412081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:42:09

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Mylene Asmar-Rios	23 Feb 2021 20:42:09

US3412081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 19:09:28



US3412081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Andrea Newlands (b) (4)	02 Mar 2021 19:09:28

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '11:22'	Andrea Newlands (b) (4)	02 Mar 2021 19:09:28

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered '23 Feb 2021 11:22'	System	02 Mar 2021 19:09:28

US3412081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:42:14

**US3412081**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:46
User entered 'I'	System	23 Feb 2021 20:42:14

**US3412081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	24 Mar 2021 16:16:26

US3412081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 07:40:47
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CALLED ACCORDING TO CLINICAL CONDUCTOR WINDOW, 3/23/2021 TO 3/29/2021' (Site from System).	Mason Urban (b) (4) (b) (4)	24 Mar 2021 16:17:23
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Mar 2021 16:16:26
User entered '24 Mar 2021'	Mason Urban (b) (4) (b) (4)	24 Mar 2021 16:16:26

**US3412081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	24 Mar 2021 16:16:26



**US3412081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	24 Mar 2021 16:16:26

US3412081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	24 Mar 2021 16:17:53

**US3412081**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:58
User entered 'I'	System	24 Mar 2021 16:17:53

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Mason Urban (b) (4)	22 Jan 2021 19:41:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Jan 2021 19:55:58
Query 'Data is required. Please complete.' answered with 'KEYED IN ERROR ON WRONG SCREEN' (Site from System).	Melissa Fuson (b) (4)	04 Jan 2021 19:51:38
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 19:48:05
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:48:05
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	04 Jan 2021 19:47:32

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '18 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 14:09:02
User entered '22 Jan 2021' reason for change: Data Entry Error	Mason Urban (b) (4)	22 Jan 2021 19:41:47
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:48:05
User entered '4 Jan 2021'	Melissa Fuson (b) (4)	04 Jan 2021 19:47:32

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:07

[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 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Mason Urban (b) (4)	22 Jan 2021 19:41:47
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:48:05
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	04 Jan 2021 19:47:32

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 19:41:47
User entered empty.	System	04 Jan 2021 19:48:05
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 19:47:32

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '18 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 14:09:14
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:42:06



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:02:42

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:42:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
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 11:02:42

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:07

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 06:15:35
Query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile. ' answered with 'information has been updated' (Site from DM).		08 Apr 2021 22:05:46
User entered '18 Jan 2021' reason for change: Data Entry Error		08 Apr 2021 22:05:31
User opened query 'Per IRT, subject was unblinded on 18JAN2021. Please review and reconcile. ' (Site from DM).		08 Apr 2021 13:03:43
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:42:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 19:42:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 19:42:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 19:42:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:42:06



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '1'	System	22 Jan 2021 19:42:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'I'	System	22 Jan 2021 19:42:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '172.5' cm	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:30:07**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '73.6' kg	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:30:07**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '24.73430'	System	22 Jan 2021 19:44:06
DataPoint set to visible.	System	22 Jan 2021 19:42:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '172.5' cm	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '73.6' kg	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:30:07**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '24.73430'	System	22 Jan 2021 19:44:06
DataPoint set to visible.	System	22 Jan 2021 19:42:06



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '11:20'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '22 Jan 2021 11:20'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '98' F	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 19:44:06



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '72'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'bpm'	System	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '16'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'breaths/min'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '130'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '80'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	22 Jan 2021 19:44:06



US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '172.5' cm	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '73.6' kg	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:30:07**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '24.73430'	System	22 Jan 2021 19:44:06
DataPoint set to visible.	System	22 Jan 2021 19:42:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13:00'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '22 Jan 2021 13:00'	System	22 Jan 2021 19:44:06



US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '98' F	Mason Urban (b) (4)	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '74'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'bpm'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '14'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'breaths/min'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '128'	Mason Urban (b) (4)	22 Jan 2021 19:44:06



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '80'	Mason Urban (b) (4)	22 Jan 2021 19:44:06

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	22 Jan 2021 19:44:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:44:13

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:44:13

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:44:26

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 19:44:26

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

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)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 19:44:26



**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mRNA-1273'	System	22 Jan 2021 19:44:26
DataPoint set to visible.	System	22 Jan 2021 19:42:06

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 19:44:26

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '12:27'	Mason Urban (b) (4)	22 Jan 2021 19:44:26

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '22 Jan 2021 12:27'	System	22 Jan 2021 19:44:26

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4)	22 Jan 2021 19:44:26

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'ONCE'	System	22 Jan 2021 19:44:26

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 19:44:26

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per GCL Lab Reconciliation: LB4- Immuno: Thank you for the response. Since 18JAN2021 is an additional sample is collected and present in PPD, Kindly consider to update as Unscheduled Immuno sample in EDC. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:24:19
Query 'Per GCL Lab Reconciliation: LB4- Immuno: Thank you for the response. Since 18JAN2021 is an additional sample is collected and present in PPD, Kindly consider to update as Unscheduled Immuno sample in EDC. ' answered with 'lab information has been updated to the 18-Jan-2021 which was the subjects original date for his unblinding decision visit. Subject presented again for his OL-day1 visit on 22-Jan-2021. The labs have been changed to unscheduled visits in the preclarus portal. please advise if there should be an unscheduled visit form filled out even though everything else was completed under OL-Day1 ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 14:11:56
User opened query 'Per GCL Lab Reconciliation: LB4- Immuno: Thank you for the response. Since 18JAN2021 is an additional sample is collected and present in PPD, Kindly consider to update as Unscheduled Immuno sample in EDC. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:28:37
User closed query 'Per GCL Lab Reconciliation: LB4- Immuno: PPD has two OL-Immuno 5 sample. 18JAN2021 with Accession# 1F616962137 as OL-D1 and 22JAN2021 with Accession# 1F600430743 as OL-D2 visit. Please review the Accession# in Preclarus to confirm the correct visit label or correct subject ID or sample label for each sample and amend EDC or Preclarus. Thank you.' (Site from DM).		23 Feb 2021 06:28:37



US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: LB4- Immuno: PPD has two OL-Immuno 5 sample. 18JAN2021 with Accession# 1F616962137 as OL-D1 and 22JAN2021 with Accession# 1F600430743 as OL-D2 visit. Please review the Accession# in Preclarus to confirm the correct visit label or correct subject ID or sample label for each sample and amend EDC or Preclarus. Thank you.' answered with 'subject originally came in for OL-D1 on 18Jan but did not receive mRNA1273 due to safety concerns. Patient returned on 22Jan2021 and received mRNA1273.   22Jan2021 is OL-D1.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 15:55:00
User opened query 'Per GCL Lab Reconciliation: LB4- Immuno: PPD has two OL-Immuno 5 sample. 18JAN2021 with Accession# 1F616962137 as OL-D1 and 22JAN2021 with Accession# 1F600430743 as OL-D2 visit. Please review the Accession# in Preclarus to confirm the correct visit label or correct subject ID or sample label for each sample and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	05 Feb 2021 11:50:45
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 19:42:28

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	15 Mar 2021 14:09:14
User closed query 'The Collection Date is prior to the System Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:09:02
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:08:45
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:08:45
User entered '18 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 14:08:45
User entered '22 Jan 2021'	(b) (4)	22 Jan 2021 19:42:28
	Mason Urban (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '12:20' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 14:08:45
User entered '11:12'	Mason Urban (b) (4)	22 Jan 2021 19:42:28

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '18 Jan 2021 12:20'	System	15 Mar 2021 14:08:45
User entered '22 Jan 2021 11:12'	System	22 Jan 2021 19:42:28

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:42:42

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		23 Apr 2021 07:31:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.'	(b) (4)	
answered with '18jan2021 should be ol-1 and 22jan2021 should be unscheduled. will be verified in ppd and updated if necessary. Please advise if the question "Has the subject reported symptoms of SARS-COV-2?" be marked as yes to populate the nasal swab ecrf even though the patient did not report any symptoms.' (Site from DM).	Andrea Newlands (b) (4)	16 Apr 2021 13:55:20
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Please confirm the correct visit to update PPD central labs, Also amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:39:09

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "subject originally came in for OL-D1 on 18Jan but did not receive mRNA1273 due to safety concerns. Patient returned on 22Jan2021 and received mRNA1273. 22Jan2021 is OL-D1." & per EDC, sample dated "22-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit; however, in PPD portal, sample with date 22-01-2021 is present for Participant Decision Visit/OL-1 visit with accession number # 1F605232149 & for sample dated 18-JAN-2021 is present as Unscheduled [1] visit with accession number #1F623747227. Kindly review the collection date, visit name, accession number and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:13:41
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "subject originally came in for OL-D1 on 18Jan but did not receive mRNA1273 due to safety concerns. Patient returned on 22Jan2021 and received mRNA1273. 22Jan2021 is OL-D1." & per EDC, sample dated "22-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit; however, in PPD portal, sample with date 22-01-2021 is present for Participant Decision Visit/OL-1 visit with accession number # 1F605232149 & for sample dated 18-JAN-2021 is present as Unscheduled [1] visit with accession number #1F623747227. Kindly review the collection date, visit name, accession number and update EDC or Preclarus portal as appropriate, else clarify.' answered with 'this is correct 18-Jan-2021 has been updated to this visit. Due to site error labs were collected again when subject represented for their OL-day 1 at a different date (22-Jan-2021) this was marked as an unscheduled visit in preclaus ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 14:13:55
User entered '18 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 14:12:25

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "subject originally came in for OL-D1 on 18Jan but did not receive mRNA1273 due to safety concerns. Patient returned on 22Jan2021 and received mRNA1273. 22Jan2021 is OL-D1." & per EDC, sample dated "22-JAN-2021" is recorded under Participant Decision Visit / OL-D1 visit; however, in PPD portal, sample with date 22-01-2021 is present for Participant Decision Visit/OL-1 visit with accession number # 1F605232149 & for sample dated 18-JAN-2021 is present as Unscheduled [1] visit with accession number #1F623747227. Kindly review the collection date, visit name, accession number and update EDC or Preclarus portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 10:19:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "18-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 07:01:29
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "18-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify.' answered with 'subject originally came in for OL-D1 on 18Jan but did not receive mRNA1273 due to safety concerns. Patient returned on 22Jan2021 and received mRNA1273. 22Jan2021 is OL-D1.' (Site from DM).	Andrea Newlands (b) (4)	12 Feb 2021 15:53:37
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "22-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "18-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:59:29



US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Jan 2021'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 19:42:42

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:30:07**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '11:15'	Mason Urban (b) (4)	22 Jan 2021 19:42:42

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:30:07**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '18 Jan 2021 11:15'	System	15 Mar 2021 14:12:25
User entered '22 Jan 2021 11:15'	System	22 Jan 2021 19:42:42

US3412081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 19:42:46

**US3412081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'I'	System	22 Jan 2021 19:42:46

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 17:50:00

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered '29 Jan 2021'	Mason Urban (b) (4)	29 Jan 2021 17:50:00

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Jan 2021 17:50:00



**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered empty.	Mason Urban (b) (4)	29 Jan 2021 17:50:00

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 17:50:04

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'I'	System	29 Jan 2021 17:50:04

**US3412081**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '1'	System	29 Jan 2021 17:50:04
DataPoint set to visible.	System	29 Jan 2021 17:50:04

**US3412081**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:44:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:44:05
	(b) (4)	

**US3412081**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[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 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:44:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'OLD29'	System	23 Feb 2021 20:44:05



**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:46:05
	(b) (4)	

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '11:19'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '23 Feb 2021 11:19'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '36.6' C	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05



**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '73'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'bpm'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '16'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'breaths/min'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '128'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '70'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	23 Feb 2021 20:46:05



**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '12:58'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '23 Feb 2021 12:58'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '97.8' F	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

US3412081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05



**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '71'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'bpm'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '16'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

US3412081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'breaths/min'	System	23 Feb 2021 20:46:05

US3412081

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '130'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '70'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:05

**US3412081**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	23 Feb 2021 20:46:05



**US3412081**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:46:23

**US3412081**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:23

**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:56

**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:56

US3412081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

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)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:56

**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User entered 'mRNA-1273'	System	23 Feb 2021 20:46:56
DataPoint set to visible.	System	29 Jan 2021 17:50:04

US3412081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '23 Feb 2021'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:56

**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '12:27'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:46:56



**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User entered '23 Feb 2021 12:27'	System	23 Feb 2021 20:46:56

US3412081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:18:56
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'per subject request different arm' (Site from System).	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:47:13
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	23 Feb 2021 20:46:56
User entered 'Right Arm (RIGHT ARM)'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:46:56

US3412081

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User entered 'ONCE'	System	23 Feb 2021 20:46:56

**US3412081**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:30:07**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 20:46:56

**US3412081**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	23 Feb 2021 20:47:20

**US3412081**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:52:52
User entered 'I'	System	23 Feb 2021 20:47:20

**US3412081**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Mar 2021 18:03:53

US3412081

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Participant Decision Visit OL-D57/OL-3 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).		21 Apr 2021 06:16:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Participant Decision Visit OL-D57/OL-3 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'this visit has been input' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 18:58:17
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24MAR2021 is recorded under Participant Decision Visit OL-D57/OL-3 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:31:21
User signature succeeded.	Richard Powell (b) (4) (b) (4)	10 Mar 2021 19:29:44
User entered '2 Mar 2021'	Mason Urban (b) (4) (b) (4)	02 Mar 2021 18:03:53



**US3412081**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	02 Mar 2021 18:03:53

**US3412081**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:30:07**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered empty.	Mason Urban (b) (4)	02 Mar 2021 18:03:53

**US3412081**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:29:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Mar 2021 18:03:59

**US3412081**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:30:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'I'	System	02 Mar 2021 18:03:59

**US3412081**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Apr 2021 18:53:53

**US3412081**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '24 Mar 2021'	Steven Anderson (b) (4)	13 Apr 2021 18:53:53

**US3412081**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[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 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	13 Apr 2021 18:53:53

**US3412081**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:30:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'OLD57'	System	13 Apr 2021 18:53:53



**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '24 Mar 2021'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '10:12'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '24 Mar 2021 10:12'	System	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '37.0' C	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (Oral)'	(b) (4)	13 Apr 2021 18:55:47
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '72'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47



**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'bpm'	System	13 Apr 2021 18:55:47

US3412081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '16'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'breaths/min'	System	13 Apr 2021 18:55:47

US3412081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '140'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	13 Apr 2021 18:55:47

US3412081

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '80'	Steven Anderson (b) (4)	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered 'mmHg'	System	13 Apr 2021 18:55:47

**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13



**US3412081**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:30:07**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13

**US3412081**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Steven Anderson (b) (4)	13 Apr 2021 18:56:07

**US3412081**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:30:07**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	13 Apr 2021 18:56:07

**US3412081**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Apr 2021 18:56:41

**US3412081**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '24 Mar 2021'	Steven Anderson (b) (4)	13 Apr 2021 18:56:41

**US3412081**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Apr 2021 18:57:03
User entered '10:28' reason for change: Data Entry Error	System	13 Apr 2021 18:57:03
User opened query 'Data is required. Please provide.' (Site from System).	Steven Anderson (b) (4)	13 Apr 2021 18:57:03
User entered empty.	(b) (4)	13 Apr 2021 18:56:41
	Steven Anderson (b) (4)	13 Apr 2021 18:56:41
	(b) (4)	

**US3412081**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:30:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:54:13
User entered '24 Mar 2021 10:28'	System	13 Apr 2021 18:57:03
User entered empty.	System	13 Apr 2021 18:56:41

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:30:07**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:28
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:28:40
User entered 'Yes (Y)'	Steven Anderson (b) (4)	18 Nov 2020 21:11:18



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
Reviewed for Safety.		19 Nov 2020 14:23:11
User entered 'USA-US061-2020-mRNA-1273-P301000012'	System	19 Nov 2020 14:23:05
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 14:23:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Klebsiella infections, PT: Pneumonia klebsiella, LLT: Pneumonia klebsiella - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Mar 2021 07:42:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:42:16
User closed query 'please add due to gram negative Klebsiella bacteria as per source' (Site from CRA). Query 'please add due to gram negative Klebsiella bacteria as per source' answered with 'this has been added per query to match site source' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 18:15:02
		16 Mar 2021 18:15:00
	Steven Anderson (b) (4)	15 Mar 2021 14:16:21
Data point term sent to Coder DataPoint Un-verified.	System Steven Anderson (b) (4)	15 Mar 2021 14:16:15 15 Mar 2021 14:16:05
Coding entries removed.	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 14:16:05
User entered 'PNEUMONIA due to gram negative Klebsiella bacteria' reason for change: Data Entry Error	(b) (4)	
User entered 'PNEUMONIA due to gram negative Klebsiella bacteria' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 14:16:05
User opened query 'please add due to gram negative Klebsiella bacteria as per source' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 19:13:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:46
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	05 Feb 2021 00:23:08 05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:16:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 21:16:48
Data point term sent to Coder	System	18 Nov 2020 21:15:38
User entered 'Pneumonia'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'No (N)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'No (N)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '13 Nov 2020'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered empty.	Steven Anderson (b) (4)	18 Nov 2020 21:15:16



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:20
	(b) (4), (b) (6)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Feb 2021 17:10:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:10:08
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	16 Mar 2021 18:15:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 19:15:57
DataPoint Verified.		13 Mar 2021 19:13:32
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).		16 Feb 2021 22:35:28
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Feb 2021 17:12:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Feb 2021 17:12:13
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 'updated' (Site from Safety).	Andrea Newlands (b) (4)	12 Feb 2021 17:10:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Feb 2021 17:10:08
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Feb 2021 17:10:08
User entered '01 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:10:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
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).		18 Dec 2020 20:22:29
DataPoint Verified.		19 Nov 2020 18:56:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered empty.	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
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).		18 Dec 2020 20:22:31
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		25 Nov 2020 19:45:31
User entered empty.	System	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
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).		24 Nov 2020 14:30:11
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:42
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 'subject has not yet been discharged from the hospital. Site will maintain contact with subject until he is discharged and then request medical records of his discharge summary. ' (Site from System).	Steven Anderson (b) (4)	18 Nov 2020 21:16:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 21:15:16
User entered 'I'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '13 Nov 2020'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:15:29
User entered '26 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:46:03
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 19:13:39
DataPoint Verified.		13 Mar 2021 19:13:37
User closed query 'PV Query: As end date for event of pneumonia was updated to 01 Jan 2021, please provide the hospital discharge date when available.' (Site from Safety).		24 Feb 2021 16:19:43
Query 'PV Query: As end date for event of pneumonia was updated to 01 Jan 2021, please provide the hospital discharge date when available.' answered with 'confirmed with source date 01 jan 2021' (Site from Safety).	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:50:45
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:50:20
User entered '01 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:50:20
User opened query 'PV Query: As end date for event of pneumonia was updated to 01 Jan 2021, please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 13:16:28
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered empty.	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '4'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:30:41
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).		16 Dec 2020 20:21:18
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'this has been updated to NA per query.' (Site from Safety).	Steven Anderson (b) (4)	16 Dec 2020 14:25:19
DataPoint Un-verified.	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Dec 2020 14:25:01
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4)	25 Nov 2020 19:45:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:42
User entered 'None (NONE)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

**US3412081**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, ANTIBIOTICS was received. Please review and add a Con Medication as appropriate or update action taken.		07 Jan 2021 13:55:53
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, ANTIBIOTICS was received. Please review and add a Con Medication as appropriate or update action taken.	Melissa Fuson (b) (4)	04 Jan 2021 18:44:37
' answered with 'UPDATED CON MEDICATIONS WITH ALL MEDICATIONS' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, ANTIBIOTICS was received. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	10 Dec 2020 05:08:33
' (Site from DM).		
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'I'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered '0'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16
	(b) (4)	



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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:15:38
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		16 Feb 2021 22:35:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	12 Feb 2021 17:12:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:12:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Jan 2021 18:18:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 18:18:30
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:45:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		19 Nov 2020 18:56:42
User entered empty.	Steven Anderson (b) (4)	18 Nov 2020 21:15:16

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Narrative = TRACE ASCITES. 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) (4), (b) (6)	15 Apr 2021 12:49:13
Query 'Per DM CLR: Narrative = TRACE ASCITES. 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 'this was deemed not clinically significant and not needed to be reported' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:14:04
User opened query 'Per DM CLR: Narrative = TRACE ASCITES. 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)	01 Apr 2021 11:42:21
User closed query 'Per DM CLR: Narrative = PASSIVE ATELECTASIS. 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).		17 Mar 2021 05:09:57
User closed query 'Per DM CLR: Narrative = A LARGE HEPATIC LESION. 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).		17 Mar 2021 05:09:44
User closed query 'Per DM CLR: Narrative = PULMONARY VASCULAR CONGESTION. 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).		17 Mar 2021 05:05:28

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = TRACE BILATERAL PLEURAL EFFUSION. 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). DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 05:05:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		16 Mar 2021 18:16:00
User closed query 'PV Query: Please provide the date of collection and type of testing of the COVID-19 test.' (Site from Safety).		16 Mar 2021 15:10:45
User closed query 'Per DM CLR: Narrative = CT ABDOMEN PELVIS WITH IV CONTRAST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		16 Mar 2021 15:09:03
User closed query 'Per DM CLR: Narrative = MRI OF THE ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		16 Mar 2021 04:57:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'this is being faxed to the given number' (Site from Safety).	Steven Anderson (b) (4)	15 Mar 2021 19:38:43
Query 'Per DM CLR: Narrative = MRI OF THE ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this has been added into con procedures' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 19:38:30

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = CT ABDOMEN PELVIS WITH IV CONTRAST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this has been updated and input under con meds' (Site from DM).	Steven Anderson (b) (4)	(b) (4) 15 Mar 2021 18:12:34

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENTS WIFE CALLED TO REPORT PATIENT ADMITTED ON 11/13 FOR COUGH AND FATIGUE. WORKUP REVEALED PNEUMONIA AND NEGATIVE COVID-19 RESULTS. PATIENT WAS IN ICU 11/14/20 TO 11/17/20 AND HAS RECEIVED ANTIBIOTIC. PATIENT WAS ADMITTED TO MERCY ANDERSON HOSPITAL. PATIENT IS EXPERIENCING DAILY IMPROVEMENT. AN X-RAY OF THE CHEST WAS COMPLETED AND LOW LONG VOLUMES, THAT IS PERSISTENT BIBASILAR AIRSPACE DISEASE REPRESENTING PNEUMONIA. CT OF THE CHEST, ABDOMIN, AND PELVIS WHERE SIGNIFICANT BILATERAL LOWER LOBE ATELECTASIS AND CONSOLIDATION WAS FOUND, WITH TRACE BILATERAL PLEURAL EFFUSIONS. ANOTHER CHEST X-RAY WHERE LEFT BASILAR AIRSPACE AND TRACE EFFUSION SUSPECTED AND PULMONARY VASCULAR CONGESTION. SUBJECT ALSO HAD A CT OF THE ABDOMEN WITH FINDINGS CONSISTENT WITH PANCREATITIS WITH AN EDEMATOUS APPEARING PANCREAS WITH PERIPANCREATIC FLUID SEEN. LARGE HYPODENSITY AGAIN SEEN IN THE LIVER WITH AREAS OF HEMORRHAGE WHICH REMAIN WITHOUT CHANGE. A CT ABSCESS DRAINAGE WITH CATH PLACEMENT WITH A FINDING OF A LARGE HYPODENSE COLLECTION SEEN IN THE LIVER. WITH AREAS OF INCREASED DENSITY SEEN WITHIN THE COLLECTION SUSPECTED TO BE PSEUDOANEURYSMS EITHER RELATED PORTAL COLLATERALS VERSUS HEPATIC VEIN. A LARGE HEPATIC LESION. AN MRI OF THE ABDOMEN WIHT FINIDINGS OF INTERSTITIAL EDEMATOUS PANCREATITIS MOST PROMINENT IN THE PANCREATIC UNCINATE PROCESS, HEAD, AND NECK. A FINDING OF CHOLELITHIASIS AND BILIARY	Steven Anderson (b) (4)	15 Mar 2021 17:35:32

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[Narrative](#)

Audit	User	Time (GMT)
SLUDGE WITHIN THE GALLBLADDER, A NEW 7.9 CM X 10.6 CM X 5.4 CM LESION, AND TRACE ASCITES SMALL TO MODERATE RIGHT PLURAL EFFUSION, AND PASSIVE ATELECTASIS IN EACH LUNG BASE. A US GALLBLADED RUQ WITH A SMALL AMOUNT OF SLUDGE WAS SEEN. A CT ABDOMEN PELVIS WITH IV CONTRAST WHERE ACUTE PANCREATITIS WITH SEVER INFLAMMATION AROUND THE HEAD AND BODY OF THE PANCREAS WAS FOUND AND PERIPORTAL EDEMA IS LIKELY SECONDARY TO THE ABOVE FINDINGS. COVID RT PCR LAB RESULTS: NOT DETECTED ON 01/07/21 AND 11/15/20' reason for change: Data Entry Error Query 'PV Query: Please provide the date of collection and type of testing of the COVID-19 test.' answered with 'lab results for this were provided. however, type of test was not' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 16:22:06

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENTS WIFE CALLED TO REPORT PATIENT ADMITTED ON 11/13 FOR COUGH AND FATIGUE. WORKUP REVEALED PNEUMONIA AND NEGATIVE COVID-19 RESULTS. PATIENT WAS IN ICU 11/14/20 TO 11/17/20 AND HAS RECEIVED ANTIBIOTIC. PATIENT WAS ADMITTED TO MERCY ANDERSON HOSPITAL. PATIENT IS EXPERIENCING DAILY IMPROVEMENT. AN X-RAY OF THE CHEST WAS COMPLETED AND LOW LONG VOLUMES, THAT IS PERSISTENT BIBASILAR AIRSPACE DISEASE REPRESENTING PNEUMONIA. CT OF THE CHEST, ABDOMIN, AND PELVIS WHERE SIGNIFICANT BILATERAL LOWER LOBE ATELECTASIS AND CONSOLIDATION WAS FOUND, WITH TRACE BILATERAL PLEURAL EFFUSIONS. ANOTHER CHEST X-RAY WHERE LEFT BASILAR AIRSPACE AND TRACE EFFUSION SUSPECTED AND PULMONARY VASCULAR CONGESTION. SUBJECT ALSO HAD A CT OF THE ABDOMEN WITH FINDINGS CONSISTENT WITH PANCREATITIS WITH AN EDEMATOUS APPEARING PANCREAS WITH PERIPANCREATIC FLUID SEEN. LARGE HYPODENSITY AGAIN SEEN IN THE LIVER WITH AREAS OF HEMORRHAGE WHICH REMAIN WITHOUT CHANGE. A CT ABSCESS DRAINAGE WITH CATH PLACEMENT WITH A FINDING OF A LARGE HYPODENSE COLLECTION SEEN IN THE LIVER. WITH AREAS OF INCREASED DENSITY SEEN WITHIN THE COLLECTION SUSPECTED TO BE PSEUDOANEURYSMS EITHER RELATED PORTAL COLLATERALS VERSUS HEPATIC VEIN. A LARGE HEPATIC LESION. AN MRI OF THE ABDOMEN WIHT FINIDINGS OF INTERSTITIAL EDEMATOUS PANCREATITIS MOST PROMINENT IN THE PANCREATIC UNCINATE PROCESS, HEAD, AND NECK. A FINDING OF CHOLELITHIASIS AND BILIARY	Steven Anderson (b) (4)	15 Mar 2021 16:21:45



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[Narrative](#)

Audit	User	Time (GMT)
SLUDGE WITHIN THE GALLBLADDER, A NEW 7.9 CM X 10.6 CM X 5.4 CM LESION, AND TRACE ASCITES SMALL TO MODERATE RIGHT PLURAL EFFUSION, AND PASSIVE ATELECTASIS IN EACH LUNG BASE. A US GALLBLADED RUQ WITH A SMALL AMOUNT OF SLUDGE WAS SEEN. A CT ABDOMEN PELVIS WITH IV CONTRAST WHERE ACUTE PANCREATITIS WITH SEVER INFLAMMATION AROUND THE HEAD AND BODY OF THE PANCREAS WAS FOUND AND PERIPORTAL EDEMA IS LIKELY SECONDARY TO THE ABOVE FINDINGS. COVID Lab results: not detected on 01/07/21 and 11/15/20' reason for change: Data Entry Error		
Query 'Per DM CLR: Narrative = A LARGE HEPATIC LESION. 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 'This is written up and documented under the liver hematoma AE' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 14:51:28
Query 'Per DM CLR: Narrative = PASSIVE ATELECTASIS. 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 'This is not going to be recorded due to falling under the scope of pneumonia, PI does not feel it is necessary to write up separately ' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 14:51:01
Query 'Per DM CLR: Narrative = PULMONARY VASCULAR CONGESTION. 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 'This is not going to be recorded due to falling under the scope of pneumonia, PI does not feel it is necessary to write up separately ' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 14:50:51

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Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = TRACE BILATERAL PLEURAL EFFUSION. 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 'This is not going to be recorded due to falling under the scope of pneumonia, PI does not feel it is necessary to write up separately ' (Site from DM). User closed query 'Please update narrative to include information from discharge documents' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 14:50:46
User opened query 'Per DM CLR: Narrative = CT ABDOMEN PELVIS WITH IV CONTRAST. 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)	11 Mar 2021 00:58:26
User opened query 'Per DM CLR: Narrative = PASSIVE ATELECTASIS. 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).		01 Mar 2021 08:05:56
User opened query 'Per DM CLR: Narrative = MRI OF THE ABDOMEN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		01 Mar 2021 08:05:48
User opened query 'Per DM CLR: Narrative = A LARGE HEPATIC LESION. 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).		01 Mar 2021 08:05:41
User opened query 'Per DM CLR: Narrative = PULMONARY VASCULAR CONGESTION. 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).		01 Mar 2021 08:05:35
		01 Mar 2021 08:05:25

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = TRACE BILATERAL PLEURAL EFFUSION. 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)	01 Mar 2021 08:05:17
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).		18 Feb 2021 13:53:12
Query 'Please update narrative to include information from discharge documents' answered with 'the narrative has been updated as much as possible' (Site from CRA).	Steven Anderson (b) (4)	17 Feb 2021 15:50:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'all relevant lab and diagnostic test results were entered that could fit.' (Site from Safety).	Steven Anderson (b) (4)	17 Feb 2021 15:50:12

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENTS WIFE CALLED TO REPORT PATIENT ADMITTED ON 11/13 FOR COUGH AND FATIGUE. WORKUP REVEALED PNEUMONIA AND NEGATIVE COVID-19 RESULTS. PATIENT WAS IN ICU 11/14/20 TO 11/17/20 AND HAS RECEIVED ANTIBIOTIC. PATIENT WAS ADMITTED TO MERCY ANDERSON HOSPITAL. PATIENT IS EXPERIENCING DAILY IMPROVEMENT. An x-ray of the chest was completed and low long volumes, that is persistent bibasilar airspace disease representing pneumonia. Ct of the chest, abdomen, and pelvis where significant bilateral lower lobe atelectasis and consolidation was found, with trace bilateral pleural effusions. Another chest x-ray where left basilar airspace and trace effusion suspected and pulmonary vascular congestion. Subject also had a CT of the abdomen with findings consistent with pancreatitis with an edematous appearing pancreas with peripancreatic fluid seen. Large hypodensity again seen in the liver with areas of hemorrhage which remain without change. a Ct abscess drainage with cath placement with a finding of a large hypodense collection seen in the liver. with areas of increased density seen within the collection suspected to be pseudoaneurysms either related portal collaterals versus hepatic vein. a large hepatic lesion. an MRI of the abdomen wiht finidings of interstitial edematous pancreatitis most prominent in the pancreatic uncinate process, head, and neck. a finding of cholelithiasis and biliary sludge within the gallbladder, a new 7.9 cm x 10.6 cm x 5.4 cm lesion, and trace ascites small to moderate right plural effusion, and passive atelectasis in each lung base. A US gallbladed RUQ with a small amount of sludge was seen. a ct abdomen pelvis with IV contrast where acute pancreatitis with sever inflammation around the head and body of the pancreas was found and periportal edema is likely secondary to the above findings.' reason for change: Data Entry Error DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	17 Feb 2021 15:49:43
	(b) (4), (b) (6)	05 Feb 2021 00:23:02

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EAB) (1725)

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Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
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).		05 Jan 2021 19:45:31
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 'ADDED ALL PROCEDURES AND MEDICATIONS TO ECRFS ' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:20:48
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 18:38:54
User opened query 'Please update narrative to include information from discharge documents' (Site from CRA).		29 Dec 2020 18:38:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		25 Nov 2020 19:45:39
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).		25 Nov 2020 19:43:03

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:42:56
User opened query 'PV Query: Please provide the date of collection and type of testing of the COVID-19 test.' (Site from Safety).		25 Nov 2020 19:42:48
DataPoint Verified.		19 Nov 2020 18:56:42
User entered 'Patients wife called to report patient admitted on 11/13 for cough and fatigue. Workup revealed pneumonia and negative COVID-19 results. patient was in ICU 11/14/20 to 11/17/20 and has received antibiotic. patient was admitted to Mercy Anderson hospital. Patient is experiencing daily improvement. We will request discharge summary upon release.'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 21:15:16

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	18 Nov 2020 21:15:16

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	18 Nov 2020 21:15:16



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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User entered 'I'	System	18 Nov 2020 21:15:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

US3412081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Obstructive pancreatitis, LLT: Biliary pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:47
Data point term sent to Coder	System	05 Feb 2021 00:23:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Obstructive pancreatitis, LLT: Biliary pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:37:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:37:15
Data point term sent to Coder	System	16 Dec 2020 14:27:17
User entered 'Acute biliary pancreatitis'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:25
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:27
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:29
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:32
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:34
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:16:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:16:35
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	12 Feb 2021 17:16:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Feb 2021 17:16:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Feb 2021 17:16:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Feb 2021 17:16:35
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4)	12 Feb 2021 17:16:35
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 17:16:35
DataPoint inactivated with code reason code Data not required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
		29 Dec 2020 18:43:38
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:26:56

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:26:56

US3412081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		05 Feb 2021 00:07:43
User closed query 'Grade 4 per source. Please confirm and update as appropriate' (Site from CRA).		05 Feb 2021 00:07:41
Query 'Grade 4 per source. Please confirm and update as appropriate' answered with 'UPDATED TO GRADE 4 PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4)	04 Jan 2021 18:21:00
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 18:20:40
User opened query 'Grade 4 per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 18:43:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		12 Jan 2021 11:53:54
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'PER MONITOR YOU CAN HAVE A GRADE 4 SEVERITY AND NO FOR A SERIOUS ADVENT' (Site from System).	Melissa Fuson (b) (4)	04 Jan 2021 19:35:34
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		04 Jan 2021 18:20:40
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:42
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:50
User entered '0'	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:26:56



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:51
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:53
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:55
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:43:57
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:43:59
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:44:03
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:44:01
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:44:05
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56



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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:44:07
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:44:08
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:44:10
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:44:13
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:45:11
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:23:48
User closed query 'Please add medication taken to conmeds log' (Site from CRA).		05 Feb 2021 00:23:45
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
Query 'Please add medication taken to conmeds log' answered with 'ADDED CONMEDS TO CONMEDS LOG' (Site from CRA).		04 Jan 2021 19:24:09
User opened query 'Please add medication taken to conmeds log' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 18:44:51
User entered 'I'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 09:22:33
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:37:37
User closed query 'Please add procedures to concomitant procedures log' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 00:23:55
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		13 Jan 2021 04:15:21
Query 'Please add procedures to concomitant procedures log' answered with 'ADDED CONPROCEDURES TO CONPROCEDURES LOG' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:24:30
User opened query 'Please add procedures to concomitant procedures log' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 18:45:09
User entered 'I'	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:26:56

US3412081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:16:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:16:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:45:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:26:56
	(b) (4)	



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:45:58
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

US3412081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:03
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:26:56

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:26:56

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '1'	System	16 Dec 2020 14:26:56

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:52:58
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 13:03:10
User entered 'USA-US061-2020-mRNA-1273-P301000012'		28 Apr 2021 13:02:50
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:44
Data point term sent to Coder	System	05 Feb 2021 00:23:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:29:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:29:54
Data point term sent to Coder	System	16 Dec 2020 14:28:17
User entered 'Acute respiratory failure'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:26
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:28
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:31
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:33
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:35
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:36
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:46:39
User entered '26 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:41
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm this G4 event does not meet seriousness criteria and update, as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 13:39:44
Query 'Per MM: Please confirm this G4 event does not meet seriousness criteria and update, as appropriate.' answered with 'information has been updated' (Site from DM).		27 Apr 2021 12:29:18
User opened query 'Per MM: Please confirm this G4 event does not meet seriousness criteria and update, as appropriate.' (Site from DM).		26 Apr 2021 18:36:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:46:42
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	27 Apr 2021 12:29:52
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	27 Apr 2021 12:23:27
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:23:27
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 12:23:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 12:23:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:46:46
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 03:52:11
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'it was medically attended at a hospital but not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:28:59
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	16 Dec 2020 14:28:14
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:46:48
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:50
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	27 Apr 2021 12:29:52
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	27 Apr 2021 12:29:52
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:29:52
Signature has been broken.		27 Apr 2021 12:29:52
User entered '1' reason for change: Data Entry Error		27 Apr 2021 12:29:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	27 Apr 2021 12:28:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:52
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 12:28:32
Signature has been broken.		27 Apr 2021 12:28:32
User entered '13 Nov 2020' reason for change: Data Entry Error		27 Apr 2021 12:28:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:54
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 12:28:32
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 12:28:32
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 12:28:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:46:55
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 12:28:32
User entered 'Yes (Y)' reason for change: Data Entry Error		27 Apr 2021 12:28:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
	(b) (4), (b) (6)	29 Dec 2020 18:46:58
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:10
	(b) (4)	
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	27 Apr 2021 12:29:52
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	27 Apr 2021 12:29:52
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	27 Apr 2021 12:28:32
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 12:28:32
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 12:28:32
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 12:28:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:47:00
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:47:01
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:47:03
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:47:05
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per CDM: As the last dose of study drug was given on 31 AUG 2020, please review and update the relationship with study drug' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 05:03:16
Query 'Per CDM: As the last dose of study drug was given on 31 AUG 2020, please review and update the relationship with study drug' answered with 'Site has updated to not related' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:28:53
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:28:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:28:26
User opened query 'Per CDM: As the last dose of study drug was given on 31 AUG 2020, please review and update the relationship with study drug' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:02:25
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:47:08
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:28:14

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 20:28:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	15 Mar 2021 20:28:26
reason for change: Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data	(b) (4), (b) (6)	05 Feb 2021 00:23:02
required.		
DataPoint inactivated with code reason code Data not		05 Feb 2021 00:22:21
required.		
DataPoint Verified.		29 Dec 2020 18:47:09
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(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 Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
		29 Dec 2020 18:47:11
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	



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None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	15 Mar 2021 20:29:19
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 20:29:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 18:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:05:09
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:49:08
User entered '1'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:52:03
Query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'this was incorrectly marked it was only a con procedure performed' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:19:14
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:18:40
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:45:55
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:29:19
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:22:52

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Concomitant Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 21:23:12
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:23:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		25 Jan 2021 11:23:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		13 Jan 2021 04:18:07
' canceled (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		13 Jan 2021 04:16:34
' (Site from DM).		
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Jan 2021 18:43:13
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 18:43:13
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:49:11
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '1' reason for change: Data Entry Error	(b) (4)	
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	13 Apr 2021 19:18:40
User closed query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the Medical Treatment Procedure recorded as there is no recorded Therapeutic procedure in the ConProc page. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 05:03:46
' (Site from DM).		
Query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the Medical Treatment Procedure recorded as there is no recorded Therapeutic procedure in the ConProc page. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.	Steven Anderson (b) (4)	15 Mar 2021 20:29:23
' answered with 'no medical procedure has been noted. Subject only received medication for treatments site removed con procedure. ' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:29:06
User opened query 'Per DM CLR - RQ: Site's response noted. However, please confirm what is the Medical Treatment Procedure recorded as there is no recorded Therapeutic procedure in the ConProc page. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 08:08:34
' (Site from DM).		
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).		17 Feb 2021 09:24:55

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 21:37:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User closed query 'Per source, action taken was a concomitant procedure. Please confirm and update here and concomitant procedure log as appropriate' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 00:08:34
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:23:20
Query 'Per source, action taken was a concomitant procedure. Please confirm and update here and concomitant procedure log as appropriate' answered with 'UPDATED CONCOMITANT PROCEDURE LOG WITH ALL PROCEDURES' (Site from CRA).	Melissa Fuson (b) (4)	04 Jan 2021 18:43:37
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 18:43:13
User opened query 'Per source, action taken was a concomitant procedure. Please confirm and update here and concomitant procedure log as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 19:05:36
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:05:11
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:49:13
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:49:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:28:14
	(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 Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:49:16
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:49:18
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:28:14



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**Form: Adverse Events (3)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 12:23:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:28:14

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**Folder: Adverse Events**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	16 Dec 2020 14:28:14

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 12:28:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:45
Data point term sent to Coder	System	05 Feb 2021 00:23:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:51:51
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:30:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:30:56
Data point term sent to Coder	System	16 Dec 2020 14:30:18
User entered 'Acute Kidney injury'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:51:52
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:51:54
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:51:56
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	



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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:51:58
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:16
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:30:05

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:18
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:20
User entered '26 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:22
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:30:05

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:24
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05



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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:26
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		17 Dec 2020 03:53:14
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this is medically attended but not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:30:20
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	16 Dec 2020 14:30:05
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:31
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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Form: Adverse Events (5)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:33
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:35
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:37
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:39
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:42
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:44
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:46
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:48
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:50
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:52
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data no required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:55
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:52:56
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:30:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	04 Jan 2021 19:26:58
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:26:58
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	04 Jan 2021 19:26:52
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:12
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:52:58
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Dec 2020 14:30:25
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Dec 2020 14:30:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	16 Dec 2020 14:30:05
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 11:07:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:39:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User closed query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA).		05 Feb 2021 00:21:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		25 Jan 2021 11:23:49
Query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' answered with 'ADDED CONMEDS TO CONMED LOG' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:27:09
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:26:52
User opened query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 19:06:22



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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:06:15
DataPoint Verified.		29 Dec 2020 18:53:00
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:02
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:53:05
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:07
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:30:05

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	16 Dec 2020 14:30:05

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:05
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic vascular disorders, PT: Hepatic haematoma, LLT: Hepatic hematoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Feb 2021 00:23:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:46
Data point term sent to Coder	System	05 Feb 2021 00:23:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data no required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:39
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic vascular disorders, PT: Hepatic haematoma, LLT: Hepatic hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:37:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:37:53
Data point term sent to Coder	System	16 Dec 2020 14:32:19
User entered 'Liver hematoma'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:53:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:43
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:45
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:47
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:49
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:31:37



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:53:51
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(b) (4)	

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**Form: Adverse Events (6)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:52
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:55
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:53:57
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:53:58
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		17 Dec 2020 03:53:37
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this was medically attended in a hospital but not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:32:24
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		16 Dec 2020 14:31:37
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:01
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

US3412081

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:03
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:04
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

US3412081

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:06
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:08
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:11
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:12
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:54:15
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:17
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:19
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37



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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:22
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:24
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

Form: Adverse Events (6)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:26
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Generated On: 09 Jun 2021 17:30:07

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:32
User entered 'I'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:54:35
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:36
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

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Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:54:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:31:37
	(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 Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:39
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37



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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:54:41
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:31:37

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:31:37

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	16 Dec 2020 14:31:37

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Klebsiella infections, PT: Klebsiella bacteraemia, LLT: Klebsiella bacteremia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	05 Feb 2021 00:23:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:43
Data point term sent to Coder	System	05 Feb 2021 00:23:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		05 Feb 2021 00:20:45
User closed query 'Please correct spacing - KLEBSIELLA is one word' (Site from CRA).		05 Feb 2021 00:20:41
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Klebsiella infections, PT: Klebsiella bacteraemia, LLT: Klebsiella bacteremia - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 23:23:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 23:23:34
Query 'Please correct spacing - KLEBSIELLA is one word' answered with 'CORRECTED SPACING OF KLEBSIELLA INTO ONE WORD' (Site from CRA).	Melissa Fuson (b) (4)	04 Jan 2021 19:28:07
Data point term sent to Coder	System	04 Jan 2021 19:27:56
Coding entries removed.	Melissa Fuson (b) (4)	04 Jan 2021 19:27:48
User entered 'KLEBSIELLA GRAM NEGATIVE BACTEREMIA' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:27:48
User opened query 'Please correct spacing - KLEBSIELLA is one word' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 18:55:27
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Klebsiella infections, PT: Klebsiella bacteraemia, LLT: Klebsiella bacteremia - version MedDRA\23.0.	Coder Import (b) (4)	16 Dec 2020 14:47:59

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:47:59
Data point term sent to Coder	(b) (4) System	16 Dec 2020 14:34:21
User entered 'Klebs iella gram negative bacteremia'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:55:51
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29



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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:55:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:55:56
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:55:58
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:00
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:33:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:56:02
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(b) (4)	

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Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:04
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:06
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:08
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

US3412081

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4)	29 Dec 2020 18:56:10
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	17 Dec 2020 03:53:53
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this was medically attended in a hospital but was not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:33:46
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	16 Dec 2020 14:33:29
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:15
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:56:16
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:18
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:20
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:56:21
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(b) (4)	



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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:23
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:24
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:26
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:28
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:29
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:31
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:33
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:35
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29



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None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:56:36
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM). DataPoint activated with code reason code Data required. DataPoint inactivated with code reason code Data not required. User closed query 'Please add medications to conmeds log' (Site from CRA). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Please add medications to conmeds log' answered with 'ADDED MEDICATIONS TO CONMEDS LOG' (Site from CRA). User opened query 'Please add medications to conmeds log' (Site from CRA).  User entered 'I'	(b) (4) (b) (4), (b) (6)  Andrea Newlands (b) (4) (b) (4)  (b) (4), (b) (6)          Melissa Fuson (b) (4) (b) (4) (b) (4), (b) (6)  Steven Anderson (b) (4) (b) (4)	15 Feb 2021 10:46:50   12 Feb 2021 17:33:26    05 Feb 2021 00:23:02 05 Feb 2021 00:22:21 05 Feb 2021 00:21:01 13 Jan 2021 04:18:26  04 Jan 2021 19:28:22  29 Dec 2020 18:57:08  16 Dec 2020 14:33:29

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:57:10
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:57:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(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 Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:57:13
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:57:16
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:33:29

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	16 Dec 2020 14:33:29



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Inflammations, PT: Systemic inflammatory response syndrome, LLT: Systemic inflammatory response syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 00:23:44
Data point term sent to Coder	System	05 Feb 2021 00:23:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Inflammations, PT: Systemic inflammatory response syndrome, LLT: Systemic inflammatory response syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:36:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 14:36:17
Data point term sent to Coder	System	16 Dec 2020 14:35:22
User entered 'Systemic inflammatory response syndrome'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:14
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:16
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:59:17
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:19
User entered '20 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:23
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	



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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:34:44

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		05 Feb 2021 00:20:19
User closed query 'End date of 26 Nov 2020 per source. Please confirm and update as appropriate' (Site from CRA).		05 Feb 2021 00:20:10
Query 'End date of 26 Nov 2020 per source. Please confirm and update as appropriate' answered with 'UPDATED END DATE PER SOURCE TO 26-NOV-2020' (Site from CRA).	Melissa Fuson (b) (4)	04 Jan 2021 19:29:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 19:29:13
User opened query 'End date of 26 Nov 2020 per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 18:58:00
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 00:20:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Jan 2021 19:30:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Jan 2021 19:30:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Jan 2021 19:29:13
User entered '26 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:29:13
DataPoint Un-verified.	(b) (4)	29 Dec 2020 18:59:28
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:59:26
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		05 Feb 2021 00:20:22
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:34:44

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:59:29
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:31
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		17 Dec 2020 03:54:00
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this was medically attended in a hospital but was not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:35:04
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	16 Dec 2020 14:34:44
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:33
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	



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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:36
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:38
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:40
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:42
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:44
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:46
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:48
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:50
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:52
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:54
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:59:56
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 18:59:58
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	16 Feb 2021 21:30:36
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:30:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Feb 2021 21:30:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:29:13
User entered '0' reason for change: Data Entry Error	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Dec 2020 14:35:12
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Dec 2020 14:35:12
User entered '1' reason for change: Data Entry Error	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Dec 2020 14:34:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
User entered '0'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 11:05:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:30:50
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:30:29
User closed query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 00:26:14
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		25 Jan 2021 11:24:18
Query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' answered with 'CONMEDS WERE ADDED TO CONMED LOG' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:30:41
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:29:13

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 19:00:59
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 19:02:19
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	



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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 19:30:24
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:02:29
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 19:02:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:34:44
	(b) (4)	

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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)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Un-verified.		29 Dec 2020 19:02:30
DataPoint Verified.		29 Dec 2020 19:02:22
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:02:33
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:34:44

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:34:44

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '1'	System	16 Dec 2020 14:34:44

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:16
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this grade 4 AE does not meet the definition of an SAE. (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 05:56:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Query 'Per MM, Please confirm if this grade 4 AE does not meet the definition of an SAE. ' answered with 'confirmed does not meet sae criteria' (Site from DM).	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 13:46:39
User opened query 'Per MM, Please confirm if this grade 4 AE does not meet the definition of an SAE. (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:11:38
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 00:23:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 00:23:46
Data point term sent to Coder	System	05 Feb 2021 00:23:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:02:57
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 14:37:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 14:37:17
Data point term sent to Coder	System	16 Dec 2020 14:36:23
User entered 'heart failure'	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:35:58



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:02:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:01
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:03
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:05
User entered '13 Nov 2020'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:06
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:42
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:45
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered empty.	System	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:47
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:48
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		17 Dec 2020 03:54:06
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this was medically attended at a hospital but not listed as serious' (Site from System).	Steven Anderson (b) (4)	16 Dec 2020 14:37:27
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	16 Dec 2020 14:35:58
User entered 'No (N)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:51
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

US3412081

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:53
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:54
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:57
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:03:59
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data no required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:02
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

US3412081

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:03
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

US3412081

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:05
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

US3412081

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:07
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:10
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 19:04:15
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:17
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:19
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:02:55
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'no medical procedure has been noted. Subject only received medication for treatments site removed con procedure.' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 20:29:46
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:29:41
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 17:42:58
DataPoint Un-verified.	Andrea Newlands (b) (4)	02 Mar 2021 19:23:20
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 19:23:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:20
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:29:41
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 19:23:20
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	15 Feb 2021 10:46:07
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Andrea Newlands (b) (4)	12 Feb 2021 17:44:10
	(b) (4)	
' answered with 'furosemide in conmeds, also taken for htn' (Site from DM).		
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User closed query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA).		05 Feb 2021 00:18:59
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		13 Jan 2021 04:18:42
' (Site from DM).		
Query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' answered with 'ADDED CONMEDS TO CONMED LOG' (Site from CRA).	Melissa Fuson (b) (4)	04 Jan 2021 19:31:01
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:41

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per source, action taken was a conmed. Please confirm and update here and conmed log as appropriate' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 19:07:40
		29 Dec 2020 19:04:23
User entered 'I'	Steven Anderson (b) (4) (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:25
User entered '0'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint Un-verified.		05 Feb 2021 00:22:21
	Melissa Fuson (b) (4)	04 Jan 2021 19:31:33
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 19:31:33
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 19:04:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:30
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
DataPoint Verified.		29 Dec 2020 19:04:31
User entered empty.	Steven Anderson (b) (4)	16 Dec 2020 14:35:58



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered '0'	System	16 Dec 2020 14:35:58

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21
User entered 'I'	System	16 Dec 2020 14:35:58

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:39:25
User entered		16 Feb 2021 22:39:14
'USA-US061-2020-mRNA-1273-P301000012'		
DataPoint activated with code reason code Data required.		05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 17:06:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 17:06:02
Data point term sent to Coder	System	12 Feb 2021 17:04:58
User entered 'cholecystitis'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '11 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Grade 4 (Grade 4)'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'As per the discharge summary, the subject was not hospitalized overnight and was discharged on the same day. If not, please reassess the reported seriousness criterion of hospitalization and retain only medically significant.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 13:01:20
Query 'As per the discharge summary, the subject was not hospitalized overnight and was discharged on the same day. If not, please reassess the reported seriousness criterion of hospitalization and retain only medically significant.' answered with 'per PI discretion this was deemed an SAE by Pi discretion ' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 20:07:37
User opened query 'As per the discharge summary, the subject was not hospitalized overnight and was discharged on the same day. If not, please reassess the reported seriousness criterion of hospitalization and retain only medically significant.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 20:13:27
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).		16 Feb 2021 22:45:40
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:03:53
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Feb 2021 22:03:46
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:47:16

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Feb 2021 17:04:12
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'PV Query: Please confirm the seriousness criteria of Life-threatening and Medically significant for the event Cholecystitis.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:05
Query 'PV Query: Please confirm the seriousness criteria of Life-threatening and Medically significant for the event Cholecystitis.' answered with 'this was changed to requiring inpatient hospitalization' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:33:57
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:31:49
User opened query 'PV Query: Please confirm the seriousness criteria of Life-threatening and Medically significant for the event Cholecystitis.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 12:49:03
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	17 Feb 2021 15:23:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
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)	15 Mar 2021 20:32:46
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	15 Mar 2021 20:32:46
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	15 Mar 2021 20:31:49
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:31:49
User entered '0'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 20:32:46
User entered empty.	Steven Anderson (b) (4)	15 Mar 2021 20:32:46
	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 20:32:46
User entered empty.	Steven Anderson (b) (4)	15 Mar 2021 20:32:46
	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Form: Adverse Events (10)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 20:32:46
User entered empty.	Steven Anderson (b) (4)	15 Mar 2021 20:32:46
DataPoint activated with code reason code Data required.	(b) (4)	12 Feb 2021 17:04:12
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
	(b) (4)	05 Feb 2021 00:23:02
	(b) (4), (b) (6)	05 Feb 2021 00:22:21



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (10)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 22:03:46
User entered '0'	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'PV Query: As the last dose of placebo was given on 31 Aug 2020, please update the action taken for the event cholecystitis from dose delayed to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:11
Query 'PV Query: As the last dose of placebo was given on 31 Aug 2020, please update the action taken for the event cholecystitis from dose delayed to not applicable.' answered with 'this has been updated per query since this happened during the OL phase and not original dosing' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:34:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:32:46
User opened query 'PV Query: As the last dose of placebo was given on 31 Aug 2020, please update the action taken for the event cholecystitis from dose delayed to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 12:47:28
User closed query 'PV Query: Please confirm action taken with study drug, as dose delayed for the event of cholecystitis. . ' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 16:24:30
Query 'PV Query: Please confirm action taken with study drug, as dose delayed for the event of cholecystitis. . ' answered with 'confirmed wit source dose delay' (Site from Safety).	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:51:56
User opened query 'PV Query: Please confirm action taken with study drug, as dose delayed for the event of cholecystitis. . ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 13:18:09
User entered 'Dose Delayed (DOSE DELAYED)'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21



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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #32 and 33 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:49:58
Query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #32 and 33 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'this field has been ticked due to there being con medications added for it' (Site from DM).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 20:04:30
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 20:08:08
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #32 and 33 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:44:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'I'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
		05 Feb 2021 00:22:21

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:21:40
User closed query 'Per CDM re-query: Thank you for updating con med eCRF. However the con meds "BRIDION 200MG IV, COLACE 100MG BID, AORESIKUNE 5MG IV" doesn't appear to be present in con med eCRF. Please review and add the con meds as appropriate else clarify. ' (Site from DM).		19 Apr 2021 06:01:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Query 'Per CDM re-query: Thank you for updating con med eCRF. However the con meds "BRIDION 200MG IV, COLACE 100MG BID, AORESIKUNE 5MG IV" doesn't appear to be present in con med eCRF. Please review and add the con meds as appropriate else clarify. ' answered with 'updated' (Site from DM).	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 13:45:44

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.  SUBJECT PRESENTED TO MERVY HEALTH AS A 72 Y/O MALE FOR ROBOTIC/LAPROSCOPIC CHOLECYSTECTOMY D/T CHOLECYSTITIS ON 13JAN2021. SURGERY WAS UNEVENTFUL AND SUBJECT WAS DISCHARGED SAME DAY. ROUTINE LABS WERE OBTAINED AND WERE WITHIN NORMAL LIMITS. MEDS GIVEN DURING STAY: BUPIVACANE - EPINEPHERINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MCG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE .2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 160 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZEMURON 50MG IV, DILAUDID .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV, APRESOLINE 5MG IV, OXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID.   SUBJECT HAS RECOVERED TO BASELINE SINCE SURGERY AND IS DOING WELL.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 16 Apr 2021 13:45:28

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.  SUBJECT PRESENTED TO MERVY HEALTH AS A 72 Y/O MALE FOR ROBOTIC/LAPROSCOPIC CHOLECYSTECTOMY D/T CHOLECYSTITIS ON 13JAN2021. SURGERY WAS UNEVENTFUL AND SUBJECT WAS DISCHARGED SAME DAY. ROUTINE LABS WERE OBTAINED AND WERE WITHIN NORMAL LIMITS. MEDS GIVEN DURING STAY: BUPIVACANE - EPINEPHERINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MCG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE .2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 160 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZEMURON 50MG IV, DILAUDID .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV, Apresoline 5MG IV, OXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6.25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID.   SUBJECT HAS RECOVERED TO BASELINE SINCE SURGERY AND IS DOING WELL. n'	Andrea Newlands (b) (4)	16 Apr 2021 13:45:14
reason for change: Data Entry Error User closed query 'Per DM CLR: Narrative = GLYCOPYCOLATE .2 MG IV. However, this is recorded as "ORAL" in the ConMed eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:51:30

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: please confirm the date of unblinding. Was the unblinding done on the same day (23 Feb 2021) when the study treatment was administered?' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:31:02
Query 'Per DM CLR: Narrative = GLYCOPYCOLATE .2 MG IV. However, this is recorded as "ORAL" in the ConMed eCRF. Please review and reconcile data as appropriate.' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4)	13 Apr 2021 19:42:37
Query 'PV Query: please confirm the date of unblinding. Was the unblinding done on the same day (23 Feb 2021) when the study treatment was administered?' answered with 'subject was unblinded on 18-jan-2021' (Site from Safety).	Steven Anderson (b) (4)	13 Apr 2021 19:42:29
User opened query 'Per DM CLR: Narrative = GLYCOPYCOLATE .2 MG IV. However, this is recorded as "ORAL" in the ConMed eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:44:23
User opened query 'PV Query: please confirm the date of unblinding. Was the unblinding done on the same day (23 Feb 2021) when the study treatment was administered?' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 20:14:35
User closed query 'Per CDM re-query: Thank you for adding medications; However there is mismatch in either name of medication / Dose / Dose unit / Route in the following medications recorded in con med: EPINEPHRINE 1MG/1ML 10 MG IV (CM #37), GLYCOPYCOLATE 2 MG IV (CM #39), PHENYLEPHRINE 100 MCG IV (CM #45), PROPROFOL 140 MCG IV (CM #46), ZENURAN 50GM IV (CM #49), DILAUDIA .5MG IV (CM #53). Please reconcile and update either narrative or con med eCRF as appropriate else clarify. Thank you.	(b) (4), (b) (6)	19 Mar 2021 06:16:50
' (Site from DM).		



US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Thank you for adding medications; However there is mismatch in either name of medication / Dose / Dose unit / Route in the following medications recorded in con med: EPINEPHRINE 1MG/1ML 10 MG IV (CM #37), GLYCOPYCOLATE 2 MG IV (CM #39), PHENYLEPHRINE 100 MCG IV (CM #45), PROPOFOL 140 MCG IV (CM #46), ZENURAN 50GM IV (CM #49), DILAUDIA .5MG IV (CM #53). Please reconcile and update either narrative or con med eCRF as appropriate else clarify. Thank you.  ' answered with '[narrative changes: epinephrine mg to mcg, glycopycolate 2 to .2, phenylephrine 100 to 160, (zenuran: to zemuron, gm to mg), dilaudia to dilaudid]  [conmed changes: propofol mg to mcg]' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	(b) (4) 18 Mar 2021 15:25:10

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.  SUBJECT PRESENTED TO MERVY HEALTH AS A 72 Y/O MALE FOR ROBOTIC/LAPROSCOPIC CHOLECYSTECTOMY D/T CHOLECYSTITIS ON 13JAN2021. SURGERY WAS UNEVENTFUL AND SUBJECT WAS DISCHARGED SAME DAY. ROUTINE LABS WERE OBTAINED AND WERE WITHIN NORMAL LIMITS. MEDS GIVEN DURING STAY: BUPIVACANE - EPINEPHERINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 McG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE .2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 160 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZEmuroN 50mg IV, DILAUDIId .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV,AORESİKUNE 5MG IV, OXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID.   SUBJECT HAS RECOVERED TO BASELINE SINCE SURGERY AND IS DOING WELL.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 18 Mar 2021 15:19:47

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.  SUBJECT PRESENTED TO MERVY HEALTH AS A 72 Y/O MALE FOR ROBOTIC/LAPROSCOPIC CHOLECYSTECTOMY D/T CHOLECYSTITIS ON 13JAN2021. SURGERY WAS UNEVENTFUL AND SUBJECT WAS DISCHARGED SAME DAY. ROUTINE LABS WERE OBTAINED AND WERE WITHIN NORMAL LIMITS. MEDS GIVEN DURING STAY: BUPIVACANE - EPINEPHERINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE 2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 100 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZENURAN 50GM IV, DILAUDIA .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV,AORESIKUNE 5MG IV, dilaudid .5mg IV, oXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID.   SUBJECT HAS RECOVERED TO BASELINE SINCE SURGERY AND IS DOING WELL.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 18 Mar 2021 14:57:42

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Thank you for updating con med eCRF. However the con meds "BRIDION 200MG IV, COLACE 100MG BID, AORESIKUNE 5MG IV" doesn't appear to be present in con med eCRF. Please review and add the con meds as appropriate else clarify.  ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:32:05
User closed query 'Per DM CLR: Per SAE Narrative "BUPIVACANE - EPINEPHRINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE 2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 100 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZENURAN 50GM IV, DILAUDIA .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV,AORESIKUNE 5MG IV, AXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID". However, some of these medications are not recorded in the CM page. Please review and reconcile as appropriate. ' (Site from DM).		17 Mar 2021 10:30:36
User opened query 'Per CDM re-query: Thank you for adding medications; However there is mismatch in either name of medication / Dose / Dose unit / Route in the following medications recorded in con med: EPINEPHRINE 1MG/1ML 10 MG IV (CM #37), GLYCOPYCOLATE 2 MG IV (CM #39), PHENYLEPHRINE 100 MCG IV (CM #45), PROPROFOL 140 MCG IV (CM #46), ZENURAN 50GM IV (CM #49), DILAUDIA .5MG IV (CM #53). Please reconcile and update either narrative or con med eCRF as appropriate else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:30:33

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please confirm whether the events of pancreatitis, pleural effusion, and hepatic lesion occurring during hospitalization for pneumonia meet the criteria for SAE reporting and update the report if necessary.' (Site from Safety). Query 'Per DM CLR: Per SAE Narrative "BUPIVACANE - EPINEPHRINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE 2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 100 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZENURAN 50GM IV, DILAUDIA .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV,AORESIKUNE 5MG IV, AXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID". However, some of these medications are not recorded in the CM page. Please review and reconcile as appropriate. ' answered with 'these medications have been added' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:12:15
Query 'PV query: Please confirm whether the events of pancreatitis, pleural effusion, and hepatic lesion occurring during hospitalization for pneumonia meet the criteria for SAE reporting and update the report if necessary.' answered with 'they all occurred during the same hospitalization and the PI deemed certain ones that met the criteria of SAE as defined in the protocol.' (Site from Safety).	Steven Anderson (b) (4)	16 Mar 2021 13:13:13
Query 'PV query: Please confirm whether the events of pancreatitis, pleural effusion, and hepatic lesion occurring during hospitalization for pneumonia meet the criteria for SAE reporting and update the report if necessary.' answered with 'they all occurred during the same hospitalization and the PI deemed certain ones that met the criteria of SAE as defined in the protocol.' (Site from Safety).	Steven Anderson (b) (4)	15 Mar 2021 20:44:06

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per SAE Narrative "BUPIVACANE - EPINEPHERINE 0.5% 20 ML INTRAPHEURAL, CETTNAXINE 2G IV, DECADRON 4MG IV, EPHEDRINE 10MG IB, EPHEDRINE 20MG IV, EPINEPHRINE 1MG/1ML 10 MG IV, FENTANYL 50 MCG IV, GLYCOPYCOLATE 2 MG IV, INDOCYANINE GREEN 12.5MG IV, LIDOCAINE 2% 50MG IV, FLAGYL 500MG IV, ZOFRAN 4MG IV, PHEYLEPHRINE 80MCG IV, PHENYLEPHRINE 100 MCG IV, PROPROFOL 140 MCG IV, ZEMURON 20 MG IV, ZENURAN 50GM IV, DILAUDIA .5MG IV, BENADRUL 12.5MG IV, LABETOLOL 5MG IV,AORESIKUNE 5MG IV, AXYCODONE 5MG PO PAIN, OXYCODONE 10MG PO PAIN, METOCLOPROMIDE 10MG IV, PHENERGAN 6,25MG IV, MORPHINE 1MG IV, BRIDION 200MG IV, COLACE 100MG BID". However, some of these medications are not recorded in the CM page. Please review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 17:42:09
User opened query 'PV query: Please confirm whether the events of pancreatitis, pleural effusion, and hepatic lesion occurring during hospitalization for pneumonia meet the criteria for SAE reporting and update the report if necessary.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 12:50:09

US3412081

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:30:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.  subject presented to mervy health as a 72 y/o male for robotic/laposcopic cholecystectomy d/t cholecystitis on 13jan2021. surgery was uneventful and subject was discharged same day. routine labs were obtained and were within normal limits. meds given during stay: bupivacane - epinephrine 0.5% 20 ml intrapheural, cettanaxine 2g iv, decadron 4mg iv, ephedrine 10mg ib, ephedrine 20mg iv, epinephrine 1mg/1ml 10 mg iv, fentanyl 50 mcg iv, glycopycolate 2 mg iv, indocyanine green 12.5mg iv, lidocaine 2% 50mg iv, flagyl 500mg iv, zofran 4mg iv, pheylephrine 80mcg iv, phenylephrine 100 mcg iv, propofol 140 mcg iv, zemuron 20 mg iv, zenuran 50gm iv, dilaudia .5mg iv, benadrul 12.5mg iv, labetolol 5mg iv,aoresikune 5mg iv, axycodone 5mg po pain, oxycodone 10mg po pain, metoclopramide 10mg iv, phenergan 6,25mg iv, morphine 1mg iv, bridion 200mg iv, colace 100mg BID.   Subject has recovered to baseline since surgery and is doing well.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 19:20:17
User entered 'HOSPITALIZATION FOR KLEBSIELLA PNEUMONIA 13NOV2020 W/ ACUTE BILIARY PANCREATITIS, ACUTE KIDNEY INJURY, AND RESPIRATORY FAILURE. S/P LAPAROSCOPIC CHOLECYSTECTOMY 13JAN2021 AS OUTPATIENT PROCEDURE DID NOT REMAIN IN HOSPITAL OVERNIGHT.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:08:12

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Hospitalization for Klesieela pneumonia 13Nov2020 w/ acute biliary pancreatitis, acute kidney injury, and respiratory failure. S/p laparoscopic cholecystectomy 13Jan2021 as outpatient procedure did not remain in hospital overnight.'	Andrea Newlands (b) (4)	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Feb 2021 17:04:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 20:32:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Feb 2021 00:23:02
DataPoint inactivated with code reason code Data not required.		05 Feb 2021 00:22:21

US3412081

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 20:54:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 20:54:05
Data point term sent to Coder	System	23 Feb 2021 20:53:48
User entered 'Melanoma'	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:53:28

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '10 Feb 2021'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:53:28

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 20:53:28

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

US3412081

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:30:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User closed query 'Per CDM re-query: Response indicates "this DOES in the opinion of the investigator". However response for is the AE serious is still No. Please update if appropriate else clarify in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 06:17:52
Query 'Per CDM re-query: Response indicates "this DOES in the opinion of the investigator". However response for is the AE serious is still No. Please update if appropriate else clarify in query response. ' answered with 'error in previous response, this does *not*' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	18 Mar 2021 15:43:56
User closed query 'Per MM, Please confirm this does not meet the definition of an SAE, medically significant.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:54:31
User opened query 'Per CDM re-query: Response indicates "this DOES in the opinion of the investigator". However response for is the AE serious is still No. Please update if appropriate else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:54:29
Query 'Per MM, Please confirm this does not meet the definition of an SAE, medically significant.' answered with 'this does in the opinion of the investigator ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:13:51
User opened query 'Per MM, Please confirm this does not meet the definition of an SAE, medically significant.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:15:06
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:53:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 20:53:47
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:53:47
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 20:53:28
User entered empty.	Mylene Asmar-Rios (b) (4)	23 Feb 2021 20:53:28



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'I'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	23 Feb 2021 20:53:28
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 20:53:47

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 20:53:28

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23

US3412081

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:30:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Magnesium metabolism disorders, PT: Hypomagnesaemia, LLT: Hypomagnesemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 14:25:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:25:05
Data point term sent to Coder	System	16 Mar 2021 14:24:45
User entered 'Hypomagnesemia'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '25 Nov 2020'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User entered empty.	System	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '25 Nov 2020'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User entered empty.	System	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 14:24:16
	(b) (4)	

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

US3412081

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:30:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

US3412081

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:30:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

US3412081

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:30:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 14:24:16
	(b) (4)	



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'I'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User entered '0'	System	16 Mar 2021 14:24:16

**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23
User entered 'I'	System	16 Mar 2021 14:24:16



**US3412081**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:53:23

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:30:07

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:28
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User closed query 'Please add Rocephin, Flagyl, piperacillin-tazobactam, magnesium sulfate, versed, and fentanyl from AEs to conmeds list per source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:18:19
Query 'Please add Rocephin, Flagyl, piperacillin-tazobactam, magnesium sulfate, versed, and fentanyl from AEs to conmeds list per source' answered with 'ADDED ALL TO CONMEDS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:44:32
User opened query 'Please add Rocephin, Flagyl, piperacillin-tazobactam, magnesium sulfate, versed, and fentanyl from AEs to conmeds list per source' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 19:11:23
User entered 'Yes (Y)' reason for change: Data Entry Error		12 Aug 2020 16:15:42
User entered 'No (N)'		07 Aug 2020 14:34:47

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 16:18:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:18:10
Data point term sent to Coder	System	12 Aug 2020 16:17:21
User entered 'Omeprazole'	(b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '40'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:03:43
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	12 Aug 2020 16:16:55
User entered 'un UNK 2009'	(b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	16 Feb 2021 21:42:54
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Aug 2020 16:16:55
	(b) (4), (b) (6)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'un UNK 2018' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 21:45:50
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 21:42:54
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 16:16:55



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User entered '1'	System	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User entered '1'	System	12 Aug 2020 16:16:55

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:28:45
User entered '804 (804)'	System	12 Aug 2020 16:16:55

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:20:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:20:05
Data point term sent to Coder	System	12 Aug 2020 16:19:22
User entered 'Losartan/HCTZ'	(b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '100/25'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:03:59
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	12 Aug 2020 16:18:47
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:18:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:18:47

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 16:22:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:22:08
Data point term sent to Coder	System	12 Aug 2020 16:21:25
User entered 'Rosuvastatin'	(b) (4), (b) (6)	12 Aug 2020 16:20:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Hyperlipidemia'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:11
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	12 Aug 2020 16:20:38
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:20:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:20:38



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 16:23:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:23:10
Data point term sent to Coder	System	12 Aug 2020 16:22:27
User entered 'Amlodipine'	(b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0.5'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:28
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	12 Aug 2020 16:21:56
User entered 'un UNK 2012'	(b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:21:56



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:21:56

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:21:56

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 16:31:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:31:10
Data point term sent to Coder	System	12 Aug 2020 16:29:40
User entered 'Trazodone'	(b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Insomnia'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '150'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:38
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	12 Aug 2020 16:28:46
User entered 'un UNK 2019'	(b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:28:46

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:28:46

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMPFETAMINE, PRODUCTSYNONYM: AMPHETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 16:33:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:33:13
Data point term sent to Coder	System	12 Aug 2020 16:32:56
User entered 'Amphetamine'	(b) (4), (b) (6)	12 Aug 2020 16:32:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ADHD'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:59
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	12 Aug 2020 16:32:10
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:32:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:32:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 16:35:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:35:11
Data point term sent to Coder	System	12 Aug 2020 16:33:58
User entered 'Alfuzosin'	(b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'BPH'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '10'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:06
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	12 Aug 2020 16:33:11
User entered 'un UNK 2013'	(b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:33:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:33:11



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Aug 2020 16:36:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:36:10
Data point term sent to Coder	System	12 Aug 2020 16:35:00
User entered 'Multivitamin'	(b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:14
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	12 Aug 2020 16:34:26
User entered 'un UNK 2010'	(b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:34:26



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:34:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:34:26

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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)	15 Mar 2021 20:54:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 20:54:33
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4)	15 Mar 2021 20:54:28 15 Mar 2021 20:53:42
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 CARPEL TUNNEL SYNDROME should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:02:55
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)	12 Feb 2021 16:08:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 16:08:48
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	12 Feb 2021 16:08:00 12 Feb 2021 16:07:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
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 CARPEL TUNNEL SYNDROME should be recorded, and update con med indication or provide clarification. ' answered with 'Indication updated- patient had carpal tunnel release surgery and took meds for pain' (Site from DM).	Andrea Newlands (b) (4)	12 Feb 2021 16:07:19
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 CARPEL TUNNEL SYNDROME should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:42:28
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)	23 Nov 2020 14:16:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:16:57
Data point term sent to Coder Coding entries removed.	System	23 Nov 2020 14:16:28
	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
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)	23 Nov 2020 14:15:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:15:55
Data point term sent to Coder	System	23 Nov 2020 14:15:27

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Norco'	Jacob sekinger (b) (4) (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please note that this medication seems to be given for a procedure, however, there is no corresponding procedure recorded in the ConProc eCRF page. Please reconcile and update to record the procedure as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 07:11:13
User entered 'CARPEL TUNNEL' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:53:42
Query 'Per DM CLR: Please note that this medication seems to be given for a procedure, however, there is no corresponding procedure recorded in the ConProc eCRF page. Please reconcile and update to record the procedure as appropriate, otherwise clarify. ' answered with 'there is no surgery subject was diagnosed with it in 2017' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that this medication seems to be given for a procedure, however, there is no corresponding procedure recorded in the ConProc eCRF page. Please reconcile and update to record the procedure as appropriate, otherwise clarify. ' answered with 'there is no surgery subject was diagnosed with it in 2017' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 20:53:36
User opened query 'Per DM CLR: Please note that this medication seems to be given for a procedure, however, there is no corresponding procedure recorded in the ConProc eCRF page. Please reconcile and update to record the procedure as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:32:05
User entered 'CARPEL TUNNEL Surgery' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 16:07:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'carpel tunnel syndrome' reason for change: Data Entry Error	System	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User entered empty.	(b) (4)	
	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered '5/325' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'mg (mg)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'as needed (PRN)' reason for change: Data Entry Error	System	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User entered empty.	(b) (4)	
	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	23 Nov 2020 14:16:18
User entered '18 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	23 Nov 2020 14:14:57
User entered empty.	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User entered empty.	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 14:16:18
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Nov 2020 14:16:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Nov 2020 14:14:57
	Jacob sekinger (b) (4)	23 Nov 2020 14:14:57
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User entered empty.	System	23 Nov 2020 14:14:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User entered empty.	System	23 Nov 2020 14:14:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:42
User entered empty.	System	23 Nov 2020 14:14:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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)	24 Nov 2020 21:45:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:45:02
Data point term sent to Coder	System	24 Nov 2020 18:38:42
User entered 'FLU VACCINE'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'GENERAL HEALTH PREVENTION'	(b) (4) Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0.5'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mL (mL)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '29 Sep 2020'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '29 Sep 2020'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User entered empty.	System	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User entered empty.	System	24 Nov 2020 18:37:48

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:46
User entered empty.	System	24 Nov 2020 18:37:48



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 11:29:56
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 Feb 2021 11:29:56
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 17:44:42 12 Feb 2021 17:43:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:03:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:03:30
Data point term sent to Coder User entered 'FUROSEMIDE'	System Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:49:21 04 Jan 2021 18:48:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'HEART FAILURE / Hypertension'	Andrea Newlands (b) (4)	12 Feb 2021 17:43:40
reason for change: Data Entry Error	(b) (4)	
User entered 'HEART FAILURE / HTN'	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '20'	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:48:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:48:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	



US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:48:38

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '26 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:48:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:48:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:48:38
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:48:38



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:48:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:48:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 17:36:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 17:36:49
Data point term sent to Coder	System	12 Feb 2021 17:22:15
Data point term sent to Coder	System	12 Feb 2021 17:21:15
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:21:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 18:50:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 18:50:31
Data point term sent to Coder	System	04 Jan 2021 18:50:22
User entered 'ZOSYN'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ACUTE BILLARY PANCREAtITIS'	(b) (4)	
reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:21:27
User entered 'ACUTE BILLARY PANCREAITIS'	(b) (4)	
reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:21:10
User entered 'ACUTE BILLARY PANCREAHITIS'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:12:25
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' ' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:41:31
User entered '4/0.5' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:41:16
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:16:56
User entered '4.5'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'g (g)'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 19:17:43
User entered 'three times daily (TID)' reason for change: Data Entry Error	System	04 Jan 2021 19:17:43
User opened query 'Data is required. Please complete.' (Site from System).	Melissa Fuson (b) (4)	04 Jan 2021 19:17:43
User entered empty.	(b) (4)	
	System	04 Jan 2021 18:50:18
	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '26 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '16 Dec 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User entered '3'	System	04 Jan 2021 19:17:43
User entered empty.	System	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User entered '1'	System	04 Jan 2021 19:17:43
User entered empty.	System	04 Jan 2021 18:50:18

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:52
User entered '804 (804)'	System	04 Jan 2021 19:17:43
User entered empty.	System	04 Jan 2021 18:50:18

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Jan 2021 18:39:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 18:39:29
Data point term sent to Coder	System	04 Jan 2021 18:52:23
User entered 'LIDOCAINE (4% PATCH))'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SURGICAL PAIN'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '4'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Other (OTHER)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'TOPICAL PATH'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Topical (TOPICAL)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:52:17
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '27 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:52:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:52:17



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:52:17
	(b) (4)	

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:52:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:52:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 20:17:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:17:30
Data point term sent to Coder	System	04 Jan 2021 18:54:24
User entered 'OXYCODINE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SURGICAL PAIN'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '5'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'four times daily (QID)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '26 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '30 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User entered '4'	System	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User entered '1'	System	04 Jan 2021 18:53:43

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:47:58
User entered '804 (804)'	System	04 Jan 2021 18:53:43



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Jan 2021 18:55:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 18:55:30
Data point term sent to Coder	System	04 Jan 2021 18:55:25
User entered 'PANTOPRAZOLE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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 GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:13:58
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 GERD should be recorded, and update con med indication or provide clarification. ' answered with 'no, subject was on omeprazole and switched to pantaprazole' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:42:28
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 GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:18:33
User entered 'GERD'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:54:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '40'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '27 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:30:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:54:39
	(b) (4)	

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:54:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:54:39



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:54:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:54:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Feb 2021 09:19:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 09:19:49
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	16 Feb 2021 21:24:51 16 Feb 2021 21:23:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Jan 2021 15:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:48:44
Data point term sent to Coder	System	04 Jan 2021 18:56:26
User entered 'POTASSIUM CHLORIDE (MCG)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:55:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:14:17
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:23:55
User entered 'acute kidney injury' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:23:50
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:19:17
User entered 'POTASSIUM BALANCE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:55:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per CDM re-query: Thank you for confirming and updating the dose and unit. However the letter 'O' is used instead of numerical '0'. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 07:35:41
Query 'Per CDM re-query: Thank you for confirming and updating the dose and unit. However the letter 'O' is used instead of numerical '0'. Please update as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	18 Mar 2021 15:47:24
User entered '20' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	18 Mar 2021 15:47:12
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 07:39:57
User opened query 'Per CDM re-query: Thank you for confirming and updating the dose and unit. However the letter 'O' is used instead of numerical '0'. Please update as appropriate. ' (Site from DM).		17 Mar 2021 07:39:55
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'the dosage number is correct however the units have been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:20:28
User entered '2o' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:55:28
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:33:31
User entered '2'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:55:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Mar 2021 12:19:34
	(b) (4)	
User entered 'ug (ug)'	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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 comment for alternate unit (use Q instead of G). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 10:58:52
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 comment for alternate unit (use Q instead of G). ' answered with 'this has been updated to mcg due to this being the actual unit of measurement' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:02:43
User entered 'MCG' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:01:56
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 comment for alternate unit (use Q instead of G). ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 00:56:44
User entered 'mEg' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:19:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:55:44



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:55:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:55:44

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '17 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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) (4), (b) (6)	17 Mar 2021 07:41:35
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 'this medication was not stopped as it is typically used with furosemide. subject is still currently on both of these' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:26:13
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:34:42
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:55:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:55:44
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:55:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:55:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:55:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:55:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 18:58:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 18:58:30
Data point term sent to Coder	System	04 Jan 2021 18:57:28
User entered 'DICLOFENAC'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'OSTEOARTHRITIS'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '75'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'as needed (PRN)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'UN UNK 2013'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:30:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:56:49
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 18:56:49

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 18:56:49

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: DUTASTERIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Jan 2021 18:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 18:59:30
Data point term sent to Coder	System	04 Jan 2021 18:58:28
User entered 'DUTASTERIDE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered 'BPH'	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0.5'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'UN UNK 2012'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:30:07

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:57:40
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:57:40

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:57:40



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: DIFLUPREDNATE, PRODUCTSYNONYM: DUREZOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 17:37:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:37:29
Data point term sent to Coder	System	04 Jan 2021 19:01:32
User entered 'DUREZOL (0.05%)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please note that these conditions and procedures are not recorded on Medical history page. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:16:39
Query 'Per DM CLR: Please note that these conditions and procedures are not recorded on Medical history page. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:55:13
User opened query 'Per DM CLR: Please note that these conditions and procedures are not recorded on Medical history page. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:30:42
User entered 'POST-OP AND CORNEAL TRANSPLANT - ANTI REJECTION. OCULAR INFLAMATION'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0.05'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Other (OTHER)'	Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'APPLICATION'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'other (OTHER)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ONE GTT OU'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:00:57



US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Topical (TOPICAL)'	Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'UN UNK 2018'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

US3412081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 19:00:57



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 19:00:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 19:00:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 12:11:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 12:11:59
Data point term sent to Coder	System	12 Feb 2021 17:34:26
Data point term sent to Coder	System	12 Feb 2021 17:24:17
Data point term sent to Coder	System	12 Feb 2021 17:20:13
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:19:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:40:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:40:50
Data point term sent to Coder	System	04 Jan 2021 19:05:38
Data point term sent to Coder	System	04 Jan 2021 19:03:34
User entered 'ROCEPHIN'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ACUTE BILIARY PACREATITIS / PNEUMONIA / KLEBSIELLA GRAM NEGATIVE BACTEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:33:54
User entered 'ACUTE BILiARY pcreatitis / pneumonia / bacteremia' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:23:52
User entered 'ACUTE BILLARy PNEUMONIA - PACCREATITIS / BACTEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:19:40
User entered 'ACUTE BILLART PNEUMONIA - PACCREATITIS / BACTEREMIA' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:05:14
User entered 'ACUTE BILICIN PNEUMONIA'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '2'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'g (g)'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '18 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:40:17
User entered 'Yes (Y)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:40:17
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User entered '1'	System	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User entered '1'	System	04 Jan 2021 19:03:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:48:19
User entered '804 (804)'	System	04 Jan 2021 19:03:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:43:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:43:56
Data point term sent to Coder	System	12 Feb 2021 17:34:26
Data point term sent to Coder	System	12 Feb 2021 17:25:18
Data point term sent to Coder	System	12 Feb 2021 17:21:14
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:20:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 18:03:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 18:03:29
Data point term sent to Coder	System	04 Jan 2021 19:05:36
User entered 'FLAGYL'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ACUTE BILLARY PACREATITIS / PNEUMONIA / KLEBSIELLA GRAM NEGATIVE BACTEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:34:01
User entered 'ACUTE BILLARY pancreatitis / pneumonia / bacteremia' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:24:21
User entered 'ACUTE BILLARY PACCREATITIS - pneumonia / BACTEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:20:35
User entered 'ACUTE BILLART PNEUMONIA - PACCREATITIS / BACTEREMIA'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '500'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '18 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:40:57
User entered 'Yes (Y)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:40:57
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User entered '3'	System	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User entered '1'	System	04 Jan 2021 19:04:57

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:02
User entered '804 (804)'	System	04 Jan 2021 19:04:57

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 19:08:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 19:08:30
Data point term sent to Coder	System	04 Jan 2021 19:07:39
User entered 'INSULIN LISPRO'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'DIABETES'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0-6' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:52:50
User entered '6'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:17:10
' (Site from DM).		
Query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.	Andrea Newlands (b) (4)	16 Feb 2021 21:52:55
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:52:50
	(b) (4)	
User opened query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.	(b) (4), (b) (6)	04 Feb 2021 07:17:16
' (Site from DM).		
User entered 'Other (OTHER)'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:52:50
User entered '0-6 - UNITS'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Subcutaneous (SUBCUTANEOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'I'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:41:25
User entered 'Yes (Y)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '27 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:41:25
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User entered '3'	System	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User entered '1'	System	04 Jan 2021 19:07:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:09
User entered '804 (804)'	System	04 Jan 2021 19:07:09



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Jan 2021 19:24:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 19:24:40
Data point term sent to Coder	System	04 Jan 2021 19:08:40
User entered 'INSULIN LISPRO'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'DIABETES'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0-3' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:53:23
User entered '3'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:17:16
Query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:53:29
User entered 'IU (IU)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:53:23
User opened query 'Per DM CLR: Please review if Dose Unit OTHER could be reported under available choice of 'IU'. If so please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:17:36
User entered 'Other (OTHER)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:53:23
User entered '0-3 UNITS'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:02:11
User entered 'other (OTHER)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please review and clarify the Frequency as this is not a known frequency for this medication. Please update the Frequency as appropriate or confirm otherwise. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:17:28
Query 'Per DM CLR: Please review and clarify the Frequency as this is not a known frequency for this medication. Please update the Frequency as appropriate or confirm otherwise. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:02:15
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	16 Feb 2021 22:02:11
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	16 Feb 2021 21:53:23
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:53:23
User opened query 'Per DM CLR: Please review and clarify the Frequency as this is not a known frequency for this medication. Please update the Frequency as appropriate or confirm otherwise. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:17:45
User entered 'H'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:08:28



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Subcutaneous (SUBCUTANEOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'I'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:41:39
User entered 'Yes (Y)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 17:41:39
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User entered '1'	System	16 Feb 2021 22:02:11
User entered empty.	System	04 Jan 2021 19:08:28



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User entered '1'	System	16 Feb 2021 22:02:11
User entered empty.	System	04 Jan 2021 19:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:14
User entered '804 (804)'	System	16 Feb 2021 22:02:11
User entered empty.	System	04 Jan 2021 19:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:53:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:38:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:38:31
Data point term sent to Coder	System	12 Feb 2021 17:34:26
Data point term sent to Coder	System	12 Feb 2021 17:25:18
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 17:25:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:49:43
Data point term sent to Coder	System	04 Jan 2021 19:46:05
User entered 'PIPERACILLIN-TAZOBACTAM' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:45:27
Data point term sent to Coder	System	04 Jan 2021 19:10:42
User entered 'PIPERACILLIN - TAZOBACTAM'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:53:43
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:53:45
User entered 'PNEUMONIA / PANCREATITIS / KLEBSIELLA GRAM NEGATIVE BACTEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:34:13
User entered 'PNEUMONIA / PANCREATITIS / BACETEREMIA' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:25:00
User entered 'PNEUMONIA - PANCREATHITS / BACETERENU'	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:17:44
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 21:48:22
User entered '3.375/50' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:48:17
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:18:54
User entered '3.375'	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'Other (OTHER)' reason for change:	Andrea Newlands (b) (4)	16 Feb 2021 21:48:17
Data Entry Error	(b) (4)	
User entered 'g (g)'	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'g/ml' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:48:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'three times daily (TID)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered '25 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:42:21
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:42:21
User entered '1'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:42:21
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered '26 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:42:21
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:10:09



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:54:06
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User entered '3'	System	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User entered '1'	System	04 Jan 2021 19:10:09

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:20
User entered '804 (804)'	System	04 Jan 2021 19:10:09

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:13:41
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:17:45
Data point term sent to Coder	System	16 Feb 2021 21:52:17
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:52:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:31:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:31:30
Data point term sent to Coder	System	04 Jan 2021 19:11:43
User entered 'MAGNESIUM SULFATE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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) (4), (b) (6)	17 Mar 2021 07:41:13
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 'An corresponding AE has been written up for this medication and indication ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:26:55
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)	01 Mar 2021 09:35:34
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 21:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 21:52:03
User entered 'Hypomagnesemia' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:52:03
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 19:11:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '2'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'g (g)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '25 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '25 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User entered empty.	System	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User entered empty.	System	04 Jan 2021 19:11:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:43
User entered empty.	System	04 Jan 2021 19:11:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 19:35:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 19:35:02
Data point term sent to Coder	System	12 Feb 2021 17:27:22
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:26:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:15:44
Data point term sent to Coder	System	04 Jan 2021 19:13:44
Data point term sent to Coder	System	04 Jan 2021 19:12:44
User entered 'VERSED'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SEDATION FOR SURGICAL PROCEDURE' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:26:43
User entered 'SEDIATION FOR SURGICAL PROCEDURE' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:13:11
User entered 'SECITRON FOR SURGICAL PROCEDURE'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'I'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User entered empty.	System	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User entered empty.	System	04 Jan 2021 19:12:38

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:47
User entered empty.	System	04 Jan 2021 19:12:38



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 19:35:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 19:35:02
Data point term sent to Coder	System	12 Feb 2021 17:26:19
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:26:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 15:15:44
Data point term sent to Coder	System	04 Jan 2021 19:14:47
User entered 'VERSED'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SEDATION FOR SURGICAL PROCEDURE' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:26:00
User entered 'SEDIATION FOR SURGICAL PROCEDURE'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'I'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User entered empty.	System	04 Jan 2021 19:14:03



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User entered empty.	System	04 Jan 2021 19:14:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:52
User entered empty.	System	04 Jan 2021 19:14:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:38:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:38:00
Data point term sent to Coder	System	12 Feb 2021 17:26:19
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 17:26:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:59:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:59:30
Data point term sent to Coder	System	04 Jan 2021 19:50:08
User entered 'FENTANYL (MCG)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:49:51
Data point term sent to Coder	System	04 Jan 2021 19:16:50
User entered 'FENTANYEL (MCG)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 19:16:31
Data point term sent to Coder	System	04 Jan 2021 19:15:48
User entered 'FENTANYE (MCG)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SEDATION FOR SURGICAL PROCEDURE' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	12 Feb 2021 17:26:08
User entered 'SEDIATION FOR SURGICAL PROCEDURE'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '50'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ug (ug)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User entered empty.	System	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User entered empty.	System	04 Jan 2021 19:15:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:51:59
User entered empty.	System	04 Jan 2021 19:15:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:24:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:24:57
Data point term sent to Coder Coding entries removed.	System	12 Feb 2021 17:26:19
	Andrea Newlands (b) (4)	12 Feb 2021 17:26:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:59:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:59:29
Data point term sent to Coder	System	04 Jan 2021 19:16:50
User entered 'FENTANYL (MCG'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'SEDATION FOR SURGICAL PROCEDURE' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Feb 2021 17:26:16
User entered 'SEDIATION FOR SURGICAL PROCEDURE'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '50'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ug (ug)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User entered empty.	System	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User entered empty.	System	04 Jan 2021 19:16:02

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:05
User entered empty.	System	04 Jan 2021 19:16:02

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 22:03:09
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 22:03:09
Data point term sent to Coder	System	16 Feb 2021 21:47:09
User entered 'omeprazole'	Andrea Newlands (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'gerd'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.		20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20'	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:46:31
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.		20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:46:31
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once daily (QD)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:46:31
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:46:31
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.		20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'un UNK 2018'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.		20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.		20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '27 Nov 2020'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
User entered '1'	System	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
User entered '1'	System	16 Feb 2021 21:46:31

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:25
User entered '804 (804)'	System	16 Feb 2021 21:46:31



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:54:56
Data point term sent to Coder	System	13 Apr 2021 19:07:11
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:06:36
User entered 'BUPIVACiNE-EPINEPHRINE .5/20' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:06:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:48:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:48:39
Data point term sent to Coder	System	16 Mar 2021 12:25:51
User entered 'Bupivacane-epinephrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystitis'	Steven Anderson (b) (4)	16 Mar 2021 12:25:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 10:58:27
' (Site from DM).		
Query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:07:23
' answered with 'this has been updated to 1 injection and the strength provided in the name' (Site from DM).		
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:06:36
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 00:55:01
' (Site from DM).		
User entered '.5/20'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Other (OTHER)'	Steven Anderson (b) (4)	16 Mar 2021 12:25:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'inj' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	13 Apr 2021 19:06:36
User entered '% /mL'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Other (OTHER)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'intrapleural'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
DataPoint Verified.		20 Apr 2021 22:18:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:25:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
User entered empty.	System	16 Mar 2021 12:25:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
User entered empty.	System	16 Mar 2021 12:25:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:29
User entered empty.	System	16 Mar 2021 12:25:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:51:41
Data point term sent to Coder	System	16 Mar 2021 12:26:52
User entered 'Ceftriaxone'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystitis'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '2'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'g (g)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
DataPoint Verified.		20 Apr 2021 22:18:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:26:39
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
User entered empty.	System	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
User entered empty.	System	16 Mar 2021 12:26:39

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:33
User entered empty.	System	16 Mar 2021 12:26:39

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 13:38:50
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 13:38:50
Data point term sent to Coder	System	16 Mar 2021 12:28:53
User entered 'Decadron'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystitis/Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '4'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:28:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
DataPoint Verified.		20 Apr 2021 22:18:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
User entered empty.	System	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
User entered empty.	System	16 Mar 2021 12:28:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:37
User entered empty.	System	16 Mar 2021 12:28:08

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:41
Data point term sent to Coder	System	16 Mar 2021 12:30:54
User entered 'Ephedrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:30:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '10'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:30:17

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.		20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:30:17
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
User entered empty.	System	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
User entered empty.	System	16 Mar 2021 12:30:17

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:52:42
User entered empty.	System	16 Mar 2021 12:30:17



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:41
Data point term sent to Coder	System	16 Mar 2021 12:31:55
User entered 'ephedrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
DataPoint Verified.		20 Apr 2021 22:18:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:31:01
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
User entered empty.	System	16 Mar 2021 12:31:01



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
User entered empty.	System	16 Mar 2021 12:31:01

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:27
User entered empty.	System	16 Mar 2021 12:31:01

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 09:41:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:41:41
Data point term sent to Coder	System	16 Mar 2021 12:32:56
User entered 'epinephrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '10'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Other (OTHER)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mcg/mL'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.		20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:32:05
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
User entered empty.	System	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
User entered empty.	System	16 Mar 2021 12:32:05

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:32
User entered empty.	System	16 Mar 2021 12:32:05

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 09:49:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:49:40
Data point term sent to Coder	System	16 Mar 2021 12:43:02
User entered 'fentanyl'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.		20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'sedation/Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '.05' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	13 Apr 2021 19:10:08
User entered '.005' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	13 Apr 2021 19:09:51
User entered '50'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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 comment for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 10:58:11
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 comment for alternate unit. ' answered with 'this dosage hs been updated to the correct one' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:11:05
User entered 'Other (OTHER)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:09:51
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 comment for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 00:55:35
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.		20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg/ml' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	13 Apr 2021 19:09:51
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.		20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.		20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.		20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:42:35



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:42:35
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
User entered empty.	System	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
User entered empty.	System	16 Mar 2021 12:42:35

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:37
User entered empty.	System	16 Mar 2021 12:42:35

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 09:43:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:43:50
Data point term sent to Coder	System	13 Apr 2021 19:44:40
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:43:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:02
Data point term sent to Coder	System	16 Mar 2021 12:44:03
User entered 'Glycopyrolate'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '.2'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	Steven Anderson (b) (4)	13 Apr 2021 19:43:43
User entered 'Oral (ORAL)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
DataPoint Verified.		20 Apr 2021 22:17:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:43:47
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
User entered empty.	System	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
User entered empty.	System	16 Mar 2021 12:43:47

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:44
User entered empty.	System	16 Mar 2021 12:43:47



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: VARIOUS, ATC: DIAGNOSTIC AGENTS, ATC: OTHER DIAGNOSTIC AGENTS, ATC: OTHER DIAGNOSTIC AGENTS, PRODUCT: INDOCYANINE GREEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 11:33:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:33:41
Data point term sent to Coder	System	16 Mar 2021 12:46:03
User entered 'indocyanine green'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '12.5'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:45:07
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
DataPoint Verified.		20 Apr 2021 22:17:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
User entered empty.	System	16 Mar 2021 12:45:07



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
User entered empty.	System	16 Mar 2021 12:45:07

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:53:49
User entered empty.	System	16 Mar 2021 12:45:07

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:31:43
Data point term sent to Coder	System	16 Mar 2021 12:47:04
User entered 'lidocane 2%'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '50'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.		20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:46:08



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:46:08
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
User entered empty.	System	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
User entered empty.	System	16 Mar 2021 12:46:08

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:03
User entered empty.	System	16 Mar 2021 12:46:08

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:53:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:53:43
Data point term sent to Coder	System	16 Mar 2021 12:48:04
User entered 'Flagyl'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystitis/ Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '500'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.		20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:47:04
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
User entered empty.	System	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
User entered empty.	System	16 Mar 2021 12:47:04

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:06
User entered empty.	System	16 Mar 2021 12:47:04

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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)	16 Mar 2021 14:08:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 14:08:02
Data point term sent to Coder	System	16 Mar 2021 12:49:05
User entered 'Zofran'	Steven Anderson (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'nausea/Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.		20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '4'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.		20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.		20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.		20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.		20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:48:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
User entered empty.	System	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
User entered empty.	System	16 Mar 2021 12:48:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:10
User entered empty.	System	16 Mar 2021 12:48:10



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:03:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:03:49
Data point term sent to Coder	System	16 Mar 2021 12:58:09
User entered 'Phenylphrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '80'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	Steven Anderson (b) (4)	13 Apr 2021 19:12:09
	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User closed query 'Per CDM: MCG is equivalent to UG. Please consider updating dose unit to UG rather than other. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 10:58:39
Query 'Per CDM: MCG is equivalent to UG. Please consider updating dose unit to UG rather than other. ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:12:30
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 19:12:09
User opened query 'Per CDM: MCG is equivalent to UG. Please consider updating dose unit to UG rather than other. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:35:58
User entered 'mcg'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.		20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.		20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.		20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.		20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:58:06
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
User entered empty.	System	16 Mar 2021 12:58:06



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
User entered empty.	System	16 Mar 2021 12:58:06

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (44)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:15
User entered empty.	System	16 Mar 2021 12:58:06

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:03:51
Data point term sent to Coder	System	16 Mar 2021 13:00:13
User entered 'Phenylephrine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.		20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '160'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.		20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ug (ug)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.		20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.		20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
DataPoint Verified.		20 Apr 2021 22:17:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 12:59:29
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
User entered empty.	System	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
User entered empty.	System	16 Mar 2021 12:59:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (45)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:19
User entered empty.	System	16 Mar 2021 12:59:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:01:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:01:53
Data point term sent to Coder	System	16 Mar 2021 13:01:13
User entered 'Propofol'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.		20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Sedation/Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.		20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '140'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	18 Mar 2021 15:20:18
	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.		20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.		20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:00:23



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:00:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
User entered empty.	System	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
User entered empty.	System	16 Mar 2021 13:00:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (46)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:40
User entered empty.	System	16 Mar 2021 13:00:23

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.		20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM BROMIDE, PRODUCTSYNONYM: ZEMURON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 13:02:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:02:50
Data point term sent to Coder	System	16 Mar 2021 13:02:13
User entered 'Zemuron'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.		20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '20'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.		20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:01:23

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.		20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.		20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:01:23
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
User entered empty.	System	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
User entered empty.	System	16 Mar 2021 13:01:23

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (47)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:50
User entered empty.	System	16 Mar 2021 13:01:23



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 13:03:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:03:50
Data point term sent to Coder	System	16 Mar 2021 13:03:14
User entered 'Flu vaccine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Yes (Y)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Influenza prophylactic'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '.5'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mL (mL)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '29 Sep 2020'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '29 Sep 2020'	Steven Anderson (b) (4)	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:02:27
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
User entered empty.	System	16 Mar 2021 13:02:27



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
User entered empty.	System	16 Mar 2021 13:02:27

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (48)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:01:56
User entered empty.	System	16 Mar 2021 13:02:27

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM BROMIDE, PRODUCTSYNONYM: ZEMURON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 13:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:04:50
Data point term sent to Coder	System	16 Mar 2021 13:04:15
User entered 'Zemuron'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '50'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.	(b) (4)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
DataPoint Verified.		20 Apr 2021 22:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:03:26
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
User entered empty.	System	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
User entered empty.	System	16 Mar 2021 13:03:26

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (49)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:00
User entered empty.	System	16 Mar 2021 13:03:26

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 13:30:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 13:30:51
Data point term sent to Coder	System	16 Mar 2021 13:05:15
User entered 'Benadryl'	Steven Anderson (b) (4)	16 Mar 2021 13:04:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '12.5'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.		20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:16:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:04:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
User entered empty.	System	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
User entered empty.	System	16 Mar 2021 13:04:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (50)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:04
User entered empty.	System	16 Mar 2021 13:04:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:17:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:17:43
Data point term sent to Coder	System	16 Mar 2021 13:06:16
User entered 'labetalol'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '5'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:05:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:05:28
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:05:28
	Steven Anderson (b) (4)	
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:05:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:05:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:05:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User entered empty.	System	16 Mar 2021 13:05:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User entered empty.	System	16 Mar 2021 13:05:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (51)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:19
User entered empty.	System	16 Mar 2021 13:05:28



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: APRESOLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 15:49:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 15:49:38
Data point term sent to Coder	System	18 Mar 2021 15:48:49
User closed query 'CDM-Coding: The trade name APNEROSINE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	18 Mar 2021 15:48:22
Query 'CDM-Coding: The trade name APNEROSINE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'updatded' (Site from System).	Andrea Newlands (b) (4)	18 Mar 2021 15:48:22
User entered 'apresoline' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Mar 2021 15:48:14
User opened query 'CDM-Coding: The trade name APNEROSINE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	17 Mar 2021 07:29:40
Data point term sent to Coder	System	16 Mar 2021 13:07:17
User entered 'apnerosine'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '5'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:06:19
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:06:19
	(b) (4)	



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:06:19
	Steven Anderson (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:06:19
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:06:19
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:06:19
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User entered empty.	System	16 Mar 2021 13:06:19



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User entered empty.	System	16 Mar 2021 13:06:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (52)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:23
User entered empty.	System	16 Mar 2021 13:06:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 08:24:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:24:00
Data point term sent to Coder	System	16 Mar 2021 13:08:17
User entered 'Dillaudiol'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '.5'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:07:29



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:07:29
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:07:29
	Steven Anderson (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:07:29
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:30:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User entered empty.	System	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User entered empty.	System	16 Mar 2021 13:07:29

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (53)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:28
User entered empty.	System	16 Mar 2021 13:07:29

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:05:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:05:43
Data point term sent to Coder	System	16 Mar 2021 13:09:18
User entered 'oxycodone'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:08:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '5'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:08:28
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:08:28
	Steven Anderson (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:08:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:08:28
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User entered empty.	System	16 Mar 2021 13:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User entered empty.	System	16 Mar 2021 13:08:28

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (54)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:32
User entered empty.	System	16 Mar 2021 13:08:28

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:21:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:21:42
Data point term sent to Coder	System	16 Mar 2021 13:09:18
User entered 'oxycodone'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:09:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '10'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:09:10
	Steven Anderson (b) (4)	
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:09:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:09:10
	Steven Anderson (b) (4)	
	(b) (4)	



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:09:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:09:10
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:09:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User entered empty.	System	16 Mar 2021 13:09:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User entered empty.	System	16 Mar 2021 13:09:10

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (55)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:37
User entered empty.	System	16 Mar 2021 13:09:10



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:13:43
Data point term sent to Coder	System	16 Mar 2021 13:11:19
User entered 'metoclopramide'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Nausea/Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '10'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:10:34



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:10:34
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:10:34
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User entered empty.	System	16 Mar 2021 13:10:34



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User entered empty.	System	16 Mar 2021 13:10:34

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (56)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:13
User entered empty.	System	16 Mar 2021 13:10:34

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:04:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:04:41
Data point term sent to Coder	System	16 Mar 2021 13:12:20
User entered 'phenergan'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'nausea/ Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '6.25'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:11:44



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4) Steven Anderson (b) (4)	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:30:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User entered empty.	System	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User entered empty.	System	16 Mar 2021 13:11:44

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (57)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:17
User entered empty.	System	16 Mar 2021 13:11:44

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:12:46
Data point term sent to Coder	System	16 Mar 2021 13:12:21
User entered 'morphine'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Cholecystectomy'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'I'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:12:19
	Steven Anderson (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:12:19
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4)	16 Mar 2021 13:12:19
	Steven Anderson (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	(b) (4)	
	Steven Anderson (b) (4)	16 Mar 2021 13:12:19
	(b) (4)	

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User entered empty.	System	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User entered empty.	System	16 Mar 2021 13:12:19

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (58)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:21
User entered empty.	System	16 Mar 2021 13:12:19

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
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.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 13:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 13:25:43
Data point term sent to Coder User entered 'dilaudid'	System Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 13:24:56 16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'pain, cholecystectomy'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '.5'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'mg (mg)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'once (ONCE)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:30:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:53
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User entered empty.	System	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User entered empty.	System	16 Apr 2021 13:24:11

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (59)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:26
User entered empty.	System	16 Apr 2021 13:24:11



US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX SODIUM, PRODUCTSYNONYM: BRIDION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 13:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 13:34:43
Data point term sent to Coder	System	16 Apr 2021 13:34:06
User entered 'bridion'	Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'anesthesia'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '200'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'mg (mg)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'unknown (UNKNOWN)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 13:33:50



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User entered empty.	System	16 Apr 2021 13:33:50



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User entered empty.	System	16 Apr 2021 13:33:50

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (60)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:30
User entered empty.	System	16 Apr 2021 13:33:50

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
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.	(b) (4) Coder Import (b) (4)	16 Apr 2021 13:36:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 13:36:41
Data point term sent to Coder User entered 'colace'	System Andrea Newlands (b) (4)	16 Apr 2021 13:36:08 16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'constipation prophylaxis'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '100'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'mg (mg)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03



**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered empty.	(b) (4)	16 Apr 2021 13:36:03
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 17:30:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User entered '2'	System	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User entered '1'	System	16 Apr 2021 13:36:03

**US3412081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (61)**

**Generated On: 09 Jun 2021 17:30:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:49
User entered '804 (804)'	System	16 Apr 2021 13:36:03

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:30:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:28
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User closed query 'Please add AE procedures' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:19:29
Query 'Please add AE procedures' answered with 'ADDED AE PROCEDURES' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:22:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:22:25
User opened query 'Please add AE procedures' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 19:12:02
User entered 'No (N)' reason for change: Data Entry Error		12 Aug 2020 16:15:15
User entered 'Yes (Y)' reason for change: Data Entry Error		12 Aug 2020 16:14:53
User entered 'No (N)'		07 Aug 2020 14:34:52

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:23:54

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'HEPATIC ANGIO'	Melissa Fuson (b) (4)	04 Jan 2021 18:23:54

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 21:36:56
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 18:33:37
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4)	04 Jan 2021 18:23:54



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:23:54

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:46
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '19 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:26:48

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'HEPATIC AV FISTULA EMBOLIZATION' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:30:59
	(b) (4)	
User entered 'HEPATIC AV FISIULA EMBOLACTION'	Melissa Fuson (b) (4)	04 Jan 2021 18:26:48
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:50
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:33:29
User entered 'Adverse Event (AE)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:26:48
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:46
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:26:48
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:50
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '20 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:33:20

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:50
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CT GUIDED CHOLECYSTOSTAMY DRAIN'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:33:20

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:50
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:45
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Melissa Fuson (b) (4)	04 Jan 2021 18:33:20
	(b) (4)	



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:41:50
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:33:20
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '25 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:34:31

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'PICCLINE'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:34:31

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:40
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:34:31
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:30:07**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:34:31

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '18 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:34:49

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'MRCP'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:34:49

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:47
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:35
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Melissa Fuson (b) (4)	04 Jan 2021 18:34:49
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:34:49

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:51
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '22 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:35:13

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:51
DataPoint Verified.		20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CARDIAC ECHO'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:35:13

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:30
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:35:13
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 17:30:07**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:35:13

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:39
DataPoint Verified.		20 Apr 2021 22:18:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '24 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:37:21

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:39
DataPoint Verified.	(b) (4)	20 Apr 2021 22:18:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CT GUIDED CHOLECYSTOSTAMY DRAIN - UPSIZED DRAIN REVISION'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:37:21

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:18:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:25
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:37:21
	(b) (4)	



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:39
DataPoint Verified.		20 Apr 2021 22:18:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:37:21
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '22 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:38:26

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'ECG'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:38:26

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:41
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:15
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Melissa Fuson (b) (4)	04 Jan 2021 18:38:26
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:41
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:38:26

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User closed query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #8 ECG (22 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 06:40:33
Query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #8 ECG (22 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' answered with 'this has been updated to the correct date' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 14:57:45
User entered '13 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 14:57:35
User opened query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #8 ECG (22 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:28:41
User entered '22 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:38:49

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'ECG'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:38:49

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:36:04
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:38:49
	(b) (4)	



**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 17:30:07**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:38:49

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '14 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:39:20

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CTAB / PELVIS with contrast' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 18:10:37
User entered 'CTAB / PELVIS'	Melissa Fuson (b) (4)	04 Jan 2021 18:39:20
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:35:58
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:20
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
DataPoint Verified.		20 Apr 2021 22:20:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:20
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:50
DataPoint Verified.		20 Apr 2021 22:20:04
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '15 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:39:33

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:50
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:04
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CTAB / PELVIS w/o contrast' reason for change: Data Entry Error	(b) (4)	
User entered 'CTAB / PELVIS'	Steven Anderson (b) (4)	15 Mar 2021 18:11:51
	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:33
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:04
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:35:52
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:33
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:04
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:39:33

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '19 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:39:50

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4)	20 Apr 2021 22:20:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CTAB with contrast' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	15 Mar 2021 18:11:20
User entered 'CTAB / PELVIS'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:50
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:35:46
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:39:50
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 17:30:07**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:20:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:39:50

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '21 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:40:11

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CTA CHEST'	Melissa Fuson (b) (4)	04 Jan 2021 18:40:11

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:35:38
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:40:11
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:40:11

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '24 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:40:37

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CTA / P / C'	Melissa Fuson (b) (4)	04 Jan 2021 18:40:37

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:34:58
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:40:37
	(b) (4)	

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 17:30:07**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:40:37

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '14 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:41:05

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'RUQ ULTRASOUND'	Melissa Fuson (b) (4)	04 Jan 2021 18:41:05

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (15)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:34:52
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:41:05
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:14
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	Melissa Fuson (b) (4)	04 Jan 2021 18:41:05

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (16)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '14 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:41:39

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CXR'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:41:39

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Feb 2021 21:34:46
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:41:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:16
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:41:39

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:19
DataPoint Verified.		20 Apr 2021 22:19:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '19 Nov 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:41:55

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CXR'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:41:55

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:19
DataPoint Verified.	(b) (4)	20 Apr 2021 22:19:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 21:34:41
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:41:55
	(b) (4)	



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:41:55

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (18)**

**Generated On: 09 Jun 2021 17:30:07**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:21
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '24 Nov 2020'	Melissa Fuson (b) (4)	04 Jan 2021 18:42:15

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:21
DataPoint Verified.		20 Apr 2021 22:19:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'CXR'	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 18:42:15

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:21
DataPoint Verified.	(b) (4)	20 Apr 2021 22:19:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 21:34:33
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Melissa Fuson (b) (4)	04 Jan 2021 18:42:15
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:21
DataPoint Verified.		20 Apr 2021 22:19:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Jan 2021 18:42:15
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:05
DataPoint Verified.		20 Apr 2021 22:19:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '13 Jan 2021'	(b) (4) Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:44:10

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:05
DataPoint Verified.		20 Apr 2021 22:19:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Cholecystectomy'	(b) (4) Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:44:10

**US3412081**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (19)**

**Generated On: 09 Jun 2021 17:30:07**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:05
DataPoint Verified.		20 Apr 2021 22:19:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 16:44:10



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:05
DataPoint Verified.		20 Apr 2021 22:19:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 16:44:10
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:09
DataPoint Verified.		20 Apr 2021 22:19:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '21 Nov 2020'	(b) (4)	
	Steven Anderson (b) (4)	15 Mar 2021 18:33:33
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'MRI of ABD w/o contrast'	Steven Anderson (b) (4)	15 Mar 2021 18:33:33

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:09
DataPoint Verified.		20 Apr 2021 22:19:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	15 Mar 2021 18:33:33

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:09
DataPoint Verified.		20 Apr 2021 22:19:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	15 Mar 2021 18:33:33
	(b) (4)	

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 17:30:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:12
DataPoint Verified.		20 Apr 2021 22:19:18
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered '21 Nov 2020'	(b) (4) Steven Anderson (b) (4) (b) (4)	15 Mar 2021 18:34:01

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 17:30:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:12
DataPoint Verified.		20 Apr 2021 22:19:18
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'MRI of Abd w contrast'	(b) (4) Steven Anderson (b) (4) (b) (4)	15 Mar 2021 18:34:01

US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 17:30:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:12
DataPoint Verified.		20 Apr 2021 22:19:18
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered 'Adverse Event (AE)'	(b) (4) Steven Anderson (b) (4) (b) (4)	15 Mar 2021 18:34:01



US3412081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 17:30:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:11:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:19:18
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:32:40
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	15 Mar 2021 18:34:01
	(b) (4)	

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



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Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	Svstem	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:01
User entered '19/Nov/2020 14:24'	System	19 Nov 2020 14:24:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'I'		19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '16/Dec/2020 14:21'	System	16 Dec 2020 20:21:59

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
User entered 'I'		16 Dec 2020 20:21:59

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '05/Jan/2021 14:45'	System	05 Jan 2021 19:45:56

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		05 Jan 2021 19:46:01
User entered 'I'		05 Jan 2021 19:45:56

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '16/Feb/2021 22:39'	System	16 Feb 2021 22:39:48



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		18 Feb 2021 13:53:44
User entered 'I'		16 Feb 2021 22:39:48

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '18/Feb/2021 08:54'	System	18 Feb 2021 13:54:06

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
User entered 'I'		18 Feb 2021 13:54:06

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '24/Feb/2021 11:24'	System	24 Feb 2021 16:25:01

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
User entered 'I'		24 Feb 2021 16:25:01

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '03/Mar/2021 12:01'	System	03 Mar 2021 17:01:14

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
User entered 'I'		03 Mar 2021 17:01:14

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '16/Mar/2021 11:24'	System	16 Mar 2021 15:24:18



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:24:23
User entered 'I'		16 Mar 2021 15:24:18

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (9)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered '19/Mar/2021 11:40'	System	19 Mar 2021 11:40:13

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 11:40:13

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (10)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
User entered '14/Apr/2021 12:31'	(b) (4) System	14 Apr 2021 16:31:37

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:31:42
User entered 'I'		14 Apr 2021 16:31:37

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (11)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:43
User entered '19/Apr/2021 06:32'	(b) (4) System	19 Apr 2021 10:32:54

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 13:04:37
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 10:32:54

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'USA-US061-2020-MRNA-1273-P301000012'	System	19 Nov 2020 14:23:05



**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:23:51
Un-reviewed for Safety.	System	15 Mar 2021 20:31:49
User entered 'No (N)'	System	15 Mar 2021 20:31:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 13:53:44
Un-reviewed for Safety.	System	17 Feb 2021 15:23:00
DataPoint Un-verified.	System	17 Feb 2021 15:23:00
User entered 'Yes (Y)'	System	17 Feb 2021 15:23:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Yes (Y)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	19 Mar 2021 11:39:50
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
DataPoint Verified.	(b) (4)	14 Apr 2021 12:08:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Feb 2021 22:39:36
Un-reviewed for Safety.	System	16 Feb 2021 22:39:14
DataPoint Un-verified.	System	16 Feb 2021 22:39:14
User entered 'Yes (Y)'	System	16 Feb 2021 22:39:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'No (N)'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Richard'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gregory'	System	19 Nov 2020 14:23:05



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'Powell'	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Gottschlich'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '4260 Glendale Milford Road'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	Svstem	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered 'Cincinnati'	System	19 Nov 2020 14:23:05

US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered 'OH'	System	14 Apr 2021 16:31:37
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:08:35
Reviewed for Safety.		19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Un-verified.	System	16 Dec 2020 20:21:59
User entered empty.	System	16 Dec 2020 20:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Dec 2020 23:27:01
User entered 'ohio'	Jacob sekinger (b) (4)	23 Nov 2020 14:26:45
	(b) (4)	

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 16:31:42
Un-reviewed for Safety.	System	14 Apr 2021 16:31:37
DataPoint Un-verified.	System	14 Apr 2021 16:31:37
User entered empty.	System	14 Apr 2021 16:31:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
DataPoint Verified.		19 Nov 2020 17:35:01
Reviewed for Safety.		19 Nov 2020 14:23:58
User entered '45242'	System	19 Nov 2020 14:23:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:13:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 11:39:50
Un-reviewed for Safety.		19 Mar 2021 11:39:47
Reviewed for Safety.		16 Dec 2020 20:33:47
DataPoint Verified.		19 Nov 2020 17:35:01
User entered 'US'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:30:07**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	28 Apr 2021 13:04:33
User entered '11'	System	19 Apr 2021 10:32:54
User entered '10'	System	14 Apr 2021 16:31:37
User entered '9'	System	19 Mar 2021 11:40:13
User entered '8'	System	16 Mar 2021 15:24:18
User entered '7'	System	03 Mar 2021 17:01:14
User entered '6'	System	24 Feb 2021 16:25:01
User entered '5'	System	18 Feb 2021 13:54:06
User entered '4'	System	16 Feb 2021 22:39:48
User entered '3'	System	05 Jan 2021 19:45:56
User entered '2'	System	16 Dec 2020 20:21:59
User entered '1'	System	19 Nov 2020 14:24:05

**US3412081**

**Folder: SAE USA-US061-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (12)**

**Generated On: 09 Jun 2021 17:30:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:23
User entered '28/Apr/2021 09:04'	(b) (4) System	28 Apr 2021 13:04:33



US3412081

Folder: SAE USA-US061-2020-MRNA-1273-P301000012

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:30:07

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:23
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 13:04:37
User entered 'I'		28 Apr 2021 13:04:33