

US3922080 (Prod: Synexus Clinical Research US, Inc. - Dallas)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:23:52

All time stamps listed in this document are displayed in GMT

US3922080

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

[Participant ID](#)

US3922080

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

US3922080

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SCRN

US3922080

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Date of Informed Consent (<i>dd MMM yyyy</i>)	3 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	HYPERTENSION
Start date (dd MMM yyyy)	20 JUN 1993
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)	JUN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	21 JAN 1997
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)	21 JAN 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN SEP 2014
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 SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2014
Start Year (derived)	2014
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2012
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 SEP 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	OBESITY
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 (6)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	CHRONIC HEPATITIS B
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	CIRRHOSIS
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	PATELLA DISLOCATED RIGHT
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	CAESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	RECONSTRUCTION OF DISLOCATED PATELLA RIGHT
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

US3922080

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	SCHIZO AFFECTIVE DISORDER
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

Condition	KNEE SURGERY RIGHT
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3922080

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 21 Apr 2021 21:56:46

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:44 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:44
Height (<i>xxx.x</i>)	170.0 cm
Weight (<i>xxx.x</i>)	133.5 kg
BMI (<i>xxx.x</i>)	46.19377 kg/m ²
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) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*) 3 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN SEP 2014

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 145382

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Height	ND - Not Done
Weight	ND - Not Done

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

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)	3 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:44
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:19
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG

US3922080

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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.

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 13:44

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

US3922080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:24 (24 HR)
Collection date and time (derived)	3 SEP 2020 12:24

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Collection date (<i>dd MMM yyyy</i>)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:47	3 SEP 2020 12:47
Nasopharyngeal Swab 2	No		

US3922080

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 14:18

PC Open Date & Time

03 SEP 2020 14:04

PC Close Date & Time

03 SEP 2020 16:34

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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 ☒

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 21:26

PC Open Date & Time 03 SEP 2020 17:29

PC Close Date & Time 04 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

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

96.1 °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

04 SEP 2020 16:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

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

06 SEP 2020 18:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 08:46

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

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

98.7 °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

08 SEP 2020 18:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:13

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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

03 SEP 2020 14:19

PC Open Date & Time

03 SEP 2020 14:04

PC Close Date & Time

03 SEP 2020 16:34

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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

03 SEP 2020 21:26

PC Open Date & Time

03 SEP 2020 17:29

PC Close Date & Time

04 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

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

04 SEP 2020 16:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

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

05 SEP 2020 18:09

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

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

06 SEP 2020 18:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 08:46

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

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

08 SEP 2020 18:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

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

09 SEP 2020 16:13

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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 ☐

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:19
PC Open Date & Time	03 SEP 2020 14:04
PC Close Date & Time	03 SEP 2020 16:34

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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 ☐

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:27
PC Open Date & Time	03 SEP 2020 17:29
PC Close Date & Time	04 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

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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US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 16:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

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)

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:42
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

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 ☒

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 08:46
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

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 ☒

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EAB) (1725)

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

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)

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:13
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3922080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 12:00
Temperature (xxx.x)	96.9 F
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)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3922080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

02 OCT 2020 13:30

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:42	2 OCT 2020 13:42
Nasopharyngeal Swab 2	No		

US3922080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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

SAFETY CALL WAS MISSED,
THIS WILL BE A PROTOCOL
DEVIATION.

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments SITE ATTEMPTED TO CONTACT
SUBJECT ON 23OCT2020,
27OCT2020 AND 28OCT2020,
MESSAGES LEFT ON
VOICEMAIL, EMAIL SENT,
CALLS NOT RETURNED.

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:03 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 09:03
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	109 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3922080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3922080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

29 OCT 2020 09:08

US3922080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:49

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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 <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"/>

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 12:25:48

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 04:19:27

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 00:30:33

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 08:04:42

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

09 JAN 2021 07:55:41

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

16 JAN 2021 02:50:31

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 05:35:46

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

30 JAN 2021 03:24:05

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 08:13:40

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

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Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:23:52

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		21 MAR 2021 08:13:51

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922080

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922080

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID

Adverse event

WORSENING OF
HYPERTENSION

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)

02 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3922080

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	USA-US212-2021-MRNA-1273-P30 1000006
Adverse event	SEPTIC SHOCK
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)	03 FEB 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)	07 FEB 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	03 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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	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	

US3922080

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

UPDATE 12/MAR/21 PT
ADMITTED TO HOSPITAL
03/FEB/21 AFTER PRESENTING
TO ER C ARM PAIN,
HYPOTENSION, ARTERIAL FIB
WITH RAPID VENTRICULAR
RESPONSE. FOUND TO HAVE
SEPTIC SHOCK AND ADMITTED
TO ICU. TREATED WITH IV
ANTIBIOTICS. CRP ABOVE 21,
ESR GRADER THEN 130, BLOOD
RETURNED
STREP-DYSGALACTIAE SEEM
TO RECOVER BUT HAD
PERSISTENT FEVER BUT
COMPLAINED OF PAIN AND
WEAKNESS OF EXTREMITIES.
STILL IN HOSPITAL AS OF
12/MAR/21 WORK UP IN
PROGRESS. WE HAVE
HOSPITAL RECORDS FROM
ADMID-24/FEB/21 SENT FOR
REST OF HER RECORDS.
SUBJECT CONTACTED SITE ON
23/FEB/20201 STATED THAT SHE
FELL IN BATHROOM AND NOW
IS CURRENTLY STILL IN
HOSPITAL UNABLE TO WALK
SUBJECT STATES SHE DID NOT
LOSE CONSCIOUSNESS . THEY
ARE RUNNING TEST. SITE
REQUESTED MEDICAL
RECORD.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	SUPERFICIAL VENOUS THROMBOSIS CEPHERIN VEIN RIGHT UE
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)	08 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 12:05:00

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	CYSTITIS
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)	03 FEB 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)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 12:05:00

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	CHRONIC NORMOCYTIC ANEMIA
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)	03 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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	CHRONIC LEFT VENTRICULAR HYPERTROPHY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	DEGENERATIVE JOINT DISEASE RIGHT KNEE AND RIGHT ANKLE
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)	03 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"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	HYPONATREMIA
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)	03 FEB 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)	24 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 12:05:00

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	USA-US212-2021-MRNA-1273-P30 1000006
Adverse event	POLYARTERITIS NODOSA
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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	03 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 12:05:00

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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	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 12:05:00

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PATIENT ADMITTED TO
HOSPITAL WITH SEPSIS. AFTER
TRANSFER OUT OF ICU
PATIENT COMPLAINED
MYALGIA, JOINT PAIN AND
UNABLE TO AMBULATE.
EXTENSIVE WORK UP WAS
DONE FOR THIS PROLONGED
HOSPITALIZATION. PATIENT
WAS DIAGNOSED WITH
POLYARTERITIS NODOSA FELT
TO BE RELATED TO CHRONIC
HEPB AND POSSIBLE COCAINE
AND OPIOID ABUSE, TREATED
WITH STEROIDS AND
ANTIVIRAL MEDICATION FOR
CHRONIC HEPB. PATIENT
DISCHARGED FROM HOSPITAL
TO REHAB.

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 12:05:00

Generated On: 10 Jun 2021 10:23:52

AEID	
Adverse event	UTI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 FEB 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)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 12:05:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 20:40:17

Generated On: 10 Jun 2021 10:23:52

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) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (1)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 JUN 1993
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING
HYPERTENSION(AE #1)

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING
HYPERTENSION(AE #1)

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:55:39

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Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 21:55:39

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LIDOCAINE 5%

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication VOLTAREN GEL

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (11)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY PAIN

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 (11)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication XARELTO

Prophylaxis Yes ☐
No ☒

Indication AE# 11 UTI

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 (12)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication AE# 11 UTI

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 (13)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication BACTRIUM DS

Prophylaxis Yes ☐
No ☒

Indication AE#5 (CYSTITIS)

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication DIFLUCAN

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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		UNKOWN
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?		Yes <input checked="" type="radio"/>
		No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication SAE#1 SEPTIC SHOCK

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SAE#1 SEPTIC SHOCK

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication SAE#3 POLYARTERITIS
NODOSA

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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 2021
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SAE#3 (POLYARTERITIS
NODOSA)

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SAE#3 (POLYARTERITIS
NODOSA)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SAE#3 (POLYARTERITIS
NODOSA)

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 21:55:39

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SAE#3 (POLYARTERITIS
NODOSA)

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2021
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (23)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication SAE#3 (POLYARTERITIS
NODOSA)

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 2.0

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ATROVENT 0.02%

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

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 (25)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LEVOPHED(8MG)

Prophylaxis Yes ☐
No ☒

Indication SAE#1(SEPTIC SHOCK)

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication PIPERACILLIN

Prophylaxis Yes ☐
No ☒

Indication SAE#1 (SEPTIC SHOCK)

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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)	UN UNK 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication SAE#1(SEPTIC SHOCK)

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 (29)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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)	UN UNK 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LACTATED RINGER

Prophylaxis Yes ☐
No ☒

Indication HYDRATION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication THIAMINE(VITAMIN B-1)

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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 (31)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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 (32)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (33)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LIDOCANE

Prophylaxis Yes ☐
No ☒

Indication TONGUE LESION BIOPSY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		UNKNOWN
Start date (dd MMM yyyy)		08 FEB 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 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 (34)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LOSARTAN HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50/12.5

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 (34)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA/VOMITING

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 (35)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication CHLORTHALIDONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FAMOTIDINE

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 (38)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication AE#10(LEFT DORSAL TONGUE
ULCERATIVE LESION)

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication SAE#3(POLYARTERITIS
NODOSA)

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 (41)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2021
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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 (42)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication SPIRIVA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 16

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
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) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2021
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
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 (43)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication SENNA

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17.2

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 (43)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FENTANTYL(1MCG)

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication NYSTATIN POWDER

Prophylaxis Yes ☐
No ☒

Indication SAE#3(POLYARTERITIS
NODOSA)

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 22 Apr 2021 21:55:39

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication UREA CREAM 10%

Prophylaxis Yes ☐
No ☒

Indication MYXEDEMA OF HANDS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ENTECAVIR

Prophylaxis Yes ☐
No ☒

Indication HEPATITIS B

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 (52)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication AE#11(URINARY TRACT
INFECTION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication AE#11 (URINARY TRACT INFECTION)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
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 (55)

Data signed: (b) (4) 22 Apr 2021 21:55:39

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Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ACUTE RENAL FAILURE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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)	UN UNK 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 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 (57)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 (57)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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 checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 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 (59)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ALBUMIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE RENAL FAILURE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	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)	UN UNK 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 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 (60)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication FOLATE/FOLIC ACID

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication ARIPIRAZOLE

Prophylaxis Yes ☐
No ☒

Indication SCHIZO AFFECTIVE DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

Name of Medication CHLORHEXIDINE GLUCONATE
0.12%

Prophylaxis Yes ☐
No ☒

Indication AE#10 (LEFT DORSAL TONGUE
ULCERATIVE LESION)

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 22 Apr 2021 21:55:39

Generated On: 10 Jun 2021 10:23:52

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

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Mar 2021 13:46:38

Generated On: 10 Jun 2021 10:23:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 15:58:25

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 FEB 2021	XR CHEST, 1 VIEW	Adverse Event	
04 FEB 2021	CT BRAIN W/O IV CONTRAST	Adverse Event	
04 FEB 2021	XR LEFT HAND, 3 OR MORE VIEWS	Adverse Event	
04 FEB 2021	XR RIGHT HAND, 3 OR MORE VIEWS	Adverse Event	
05 FEB 2021	CT CERVICAL SPINE, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT LOWER EXTREMITY RIGHT, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT UPPER EXTREMITY RIGHT, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT UPPER EXTREMITY LEFT, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT LOWER EXTREMITY LEFT, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT CHEST, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT ABDOMEN/PELVIS, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT THORACIC SPINE, W/O IV CONTRAST	Adverse Event	
05 FEB 2021	CT LUMBAR SPINE, W/O IV CONTRAST	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Data signed: (b) (4) 22 Apr 2021 15:58:25

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 FEB 2021	XR CHEST 1 VIEW	Adverse Event	
07 FEB 2021	MAXIILLOFACIAL CT, W/O IV CONTRAST	Adverse Event	
08 FEB 2021	US DOPPLER VENOUS DVT LOWER EXTREMITY BILATERAL	Adverse Event	
08 FEB 2021	US DOPPLER VENOUS DVT UPPER EXTREMITY RIGHT	Adverse Event	
10 FEB 2021	XR CHEST 1 VIEW	Adverse Event	
20 FEB 2021	'XR RIGHT ANKLE, 2 VIEWS'	Adverse Event	
20 FEB 2021	XR LEFT ANKLE, 2 VIEWS	Adverse Event	
20 FEB 2021	XR TIBIA FIBULA RIGHT, 2 VIEWS	Adverse Event	
20 FEB 2021	XR RIGHT KNEE, 2 OR LESS VIEWS	Adverse Event	
21 FEB 2021	XR CHEST, 1 VIEW	Adverse Event	
08 FEB 2021	BIOPSY LEFT DORSAL TONGUE ULCERATIVE LESION	Diagnostic	

US3922080

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Mar 2021 14:34:16

Generated On: 10 Jun 2021 10:23:52

Date of dosing discontinuation (dd MMM yyyy) 02 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1

US3922080

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 14 Apr 2021 17:15:36

Generated On: 10 Jun 2021 10:23:52

Date of study discontinuation/completion (dd MMM yyyy) 25 FEB 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input checked="" type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	05/MAR/2021 15:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:12
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

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	15/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

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	25/MAR/2021 06:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	09/APR/2021 09:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	15/APR/2021 14:39
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

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/APR/2021 09:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/APR/2021 06:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	21/APR/2021 09:42
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

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (10)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	22/APR/2021 06:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (11)

Data signed: (b) (4) 26 Apr 2021 13:58:53

Generated On: 10 Jun 2021 10:23:52

SAEID	USA-US212-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	23/APR/2021 12:25
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

US3922080 (Prod: Synexus Clinical Research US, Inc. - Dallas)

US3922080

Form: Participant Creation

Generated On: 10 Jun 2021 10:23:52

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:27
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User entered 'US3922080'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:58

US3922080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:16
User entered 'Yes (Y)'	Chana Hines (b) (4)	03 Sep 2020 19:02:19

US3922080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:16
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:59

US3922080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:16
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	03 Sep 2020 19:02:19

US3922080

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'SCRN'	System	03 Sep 2020 19:02:19

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered (b) (6) 1973' reason for change: Data Entry Error	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:34:43
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:25:00

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:34
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	10 Sep 2020 16:40:13
User entered '46' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	10 Sep 2020 16:40:13
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	04 Sep 2020 21:23:08
User entered '43'	Lorine Cook (b) (4) (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'YEARS'	System	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered '46'	System	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered 'Female (F)'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered 'I'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4) (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered empty.	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:23:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:34
User entered '0'	Lorine Cook (b) (4)	04 Sep 2020 21:23:08

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered '3 Sep 2020'	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'Sep 2020'	System	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered '2020'	System	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered 'Amendment 3 (3)'	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered 'Yes (Y)'	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered empty.	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered empty.	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered 'No (N)'	Chana Hines (b) (4)	03 Sep 2020 19:02:53

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:02:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 16:24:59

US3922080

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:23:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'I'	System	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:23:52

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:02:48
User entered 'Yes (Y)'	Chana Hines (b) (4)	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:23:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:58:30
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:32:44

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:34:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:34:44
Data point term sent to Coder	System	09 Sep 2020 14:34:14
User entered 'Hypertension'	Patrick Brooks (b) (4) (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
Signature has been broken.	(b) (4) lynn yauch (b) (4)	19 Apr 2021 21:31:13
User signature succeeded.	(b) (4) Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '20 Jun 1993'	Patrick Brooks (b) (4) (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
Signature has been broken.	Lorine Cook (b) (4)	21 Apr 2021 17:50:47
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
Signature has been broken.	lynn yauch (b) (4)	19 Apr 2021 21:30:51
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jun 1993'	System	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	09 Sep 2020 14:33:50

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User closed query 'Per MM: please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 19:25:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:26
Data point term sent to Coder	System	05 Oct 2020 16:44:24
Query 'Per MM: please expand the abbreviation' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:44:11
Coding entries removed.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:44:01
User entered 'Cesarean SECTION' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:44:01
User opened query 'Per MM: please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:14:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:35:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:35:48
Data point term sent to Coder	System	09 Sep 2020 14:35:15
User entered 'C-Section'	Patrick Brooks (b) (4) (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '21 Jan 1997'	Patrick Brooks (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '21 Jan 1997'	Patrick Brooks (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	09 Sep 2020 14:34:42

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:37:58
Data point term sent to Coder	System	09 Sep 2020 14:36:17
User entered 'Hysterectomy'	Patrick Brooks (b) (4) (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'UN Sep 2014'	Patrick Brooks (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'UN Sep 2014'	Patrick Brooks (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Sep 2014'	System	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '2014'	System	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Sep 2014'	System	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '2014'	System	09 Sep 2020 14:35:30

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:47:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:47:18
Data point term sent to Coder	System	05 Oct 2020 16:46:27
User entered 'menorrhagia'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'un UNK 2012'	lynn yauch (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'un Sep 2014'	lynn yauch (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 2012'	System	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '2012'	System	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Sep 2014'	System	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '2014'	System	05 Oct 2020 16:46:00

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:59:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:47:17
Data point term sent to Coder	System	05 Oct 2020 16:46:28
User entered 'obesity'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'un UNK 2010'	lynn yauch (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 2010'	System	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '2010'	System	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	05 Oct 2020 16:46:21

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User closed query 'Please note source only documents hysterectomy on un sep 2014; no post menopausal documented. Please review and determine if this needs to be removed from EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 13:50:02
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 06:32:32
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)	15 Mar 2021 15:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 15:40:57
Data point term sent to Coder	System	15 Mar 2021 15:39:44
User entered 'hyperlipidemia' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:38:44
Data point term sent to Coder	System	15 Mar 2021 15:38:43
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
Data point term sent to Coder	System	06 Nov 2020 19:55:58
DataPoint inactivated with code reason code Data not required.	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
Query 'Please note source only documents hysterectomy on un sep 2014; no post menopausal documented. Please review and determine if this needs to be removed from EDC. Thank you.' answered with 'corrected ' (Site from CRA).	Lorine Cook (b) (4)	06 Nov 2020 19:53:23
Query 'Data is required. Please complete.' answered with 'no data ' (Site from System).	Lorine Cook (b) (4)	06 Nov 2020 19:53:15
Data point term sent to Coder	System	06 Nov 2020 19:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:52:36
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	06 Nov 2020 19:52:36

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Please note source only documents hysterectomy on un sep 2014; no post menopausal documented. Please review and determine if this needs to be removed from EDC. Thank you.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:00:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 13:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 13:06:35
Data point term sent to Coder	System	21 Oct 2020 13:04:54
User entered 'post menopausal'	lynn yauch (b) (4)	21 Oct 2020 13:03:57
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
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 15:38:44
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	06 Nov 2020 19:52:36
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	06 Nov 2020 19:52:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'un Sep 2014'	lynn yauch (b) (4)	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	15 Mar 2021 15:38:44
DataPoint activated with code reason code Data required.	(b) (4)	
	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4)	21 Oct 2020 13:03:57
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	15 Mar 2021 15:38:51
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:38:51
DataPoint activated with code reason code Data required.	lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:55:08
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 19:53:32
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:53:32
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
DataPoint activated with code reason code Data required.	(b) (4) lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4) Lorine Cook (b) (4)	06 Nov 2020 19:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered empty.	lynn yauch (b) (4) (b) (4)	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:26
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
DataPoint activated with code reason code Data required.	(b) (4) lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4) Lorine Cook (b) (4)	06 Nov 2020 19:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:59:27
User entered '0'	lynn yauch (b) (4) (b) (4)	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
User entered empty.	(b) (4)	
	System	06 Nov 2020 19:52:36
User entered 'Sep 2014'	System	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
User entered empty.	(b) (4)	
	System	06 Nov 2020 19:52:36
User entered '2014'	System	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4)	06 Nov 2020 19:55:08
User entered empty.	Lorine Cook (b) (4)	21 Oct 2020 13:03:57
	System	

US3922080

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	15 Mar 2021 15:38:12
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lorine Cook (b) (4)	06 Nov 2020 19:55:08
	(b) (4)	
User entered empty.	System	21 Oct 2020 13:03:57

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Chronic hepatitis B, LLT: Chronic hepatitis B - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 15:43:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 15:43:58
Data point term sent to Coder	System	15 Mar 2021 15:42:48
User entered 'chronic hepatitis B'	lynn yauch (b) (4)	15 Mar 2021 15:42:23
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered 'un UNK 1993' reason for change:	(b) (4)	
Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:46:48
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	15 Mar 2021 15:42:23
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered '0' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	15 Mar 2021 15:46:48
User entered '1'	(b) (4)	
	lynn yauch (b) (4)	15 Mar 2021 15:42:23
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:06
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	15 Mar 2021 15:46:48
User entered empty.	System	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	15 Mar 2021 15:46:48
User entered empty.	System	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	15 Mar 2021 15:42:23

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:31:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:31:11
Data point term sent to Coder	System	16 Apr 2021 18:29:48
User entered 'obstructive sleep apnea'	lynn yauch (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:10
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:11

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Psychiatric disorders, HLTG: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Cocaine abuse - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:31:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:31:10
Data point term sent to Coder	System	16 Apr 2021 18:29:49
User entered 'cocaine abuse'	lynn yauch (b) (4)	16 Apr 2021 18:29:34
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:34

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:01:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:29:34

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Treponema infections, PT: Syphilis, LLT: Syphilis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Apr 2021 08:22:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:22:35
Data point term sent to Coder	System	16 Apr 2021 18:32:05
User entered 'syphilis infection'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:10:04
User closed query 'Please clarify selections for question, source states unknown under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:09:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 09:51:36
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Lorine Cook (b) (4)	20 Apr 2021 18:30:38
Query 'Please clarify selections for question, source states unknown under Stop Date or Ongoing, please review source against EDC and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 18:30:19
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 18:30:01
Signature has been broken.	Lorine Cook (b) (4)	20 Apr 2021 18:30:01
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 18:30:01
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:10:29
User opened query 'Please clarify selections for question, source states unknown under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:10:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4)	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:02:03
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:31:19

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:31:19

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:38:56
Data point term sent to Coder	System	16 Apr 2021 18:38:12
User entered 'chronic obstructive pulmonary disease'	lynn yauch (b) (4)	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User closed query 'Please clarify selections for question, source is blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:38:56
Query 'Please clarify selections for question, source is blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 17:09:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User opened query 'Please clarify selections for question, source is blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:11:13
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:37:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 18:37:51
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 18:37:51
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:37:39
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:11:28
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:37:51
User entered '1'	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:37:39
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:37:39

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure chronic, LLT: Chronic heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:38:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:38:57
Data point term sent to Coder	System	16 Apr 2021 18:38:12
User entered 'chronic heart failure'	lynn yauch (b) (4)	16 Apr 2021 18:38:07
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User closed query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:40:07
Query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 17:13:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User opened query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:12:13
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:38:07
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:12:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:07

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis liver - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 18:40:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:40:13
Data point term sent to Coder	System	16 Apr 2021 18:39:13
User entered 'cirrhosis'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:22
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:34

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:40:44
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:40:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:40:13
Data point term sent to Coder	System	16 Apr 2021 18:39:13
User entered 'anxiety'	lynn yauch (b) (4)	16 Apr 2021 18:38:52
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:41:50
User closed query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:41:33
Query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 17:19:52
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:14:23
User opened query 'Please clarify selections for question, source currently blank under Stop Date or Ongoing, please review source against EDC and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:14:20
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4)	16 Apr 2021 18:38:52
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:13:50
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:38:52

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 18:40:16
User entered 'Gastroesophageal reflux disease'	lynn yauch (b) (4)	16 Apr 2021 18:39:48
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:55
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:39:48

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Apr 2021 18:42:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:42:08
Data point term sent to Coder	System	16 Apr 2021 18:41:17
User entered 'headaches'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:51
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:19

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 18:42:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:42:10
Data point term sent to Coder	System	16 Apr 2021 18:41:18
User entered 'uterine fibroids'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:48
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:41

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:42:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:42:09
Data point term sent to Coder	System	16 Apr 2021 18:41:17
User entered 'depression'	lynn yauch (b) (4)	16 Apr 2021 18:40:56
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:41
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:40:56

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Joint dislocation, LLT: Dislocated patella - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 11:54:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 11:54:30
Data point term sent to Coder	System	16 Apr 2021 18:43:19
User entered 'patella dislocated right'	lynn yauch (b) (4)	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'UN UNK 1997' reason for change:	(b) (4)	
Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 18:45:47
User entered 'un UNK 1995'	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:42:25
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1997' reason for change:	(b) (4)	
Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 18:45:33
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:42:25
	(b) (4)	

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:32
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User closed query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	16 Apr 2021 18:45:51
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 18:45:51
User opened query 'Ongoing is reported as No, but Stop Date is provided and Stop Date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	16 Apr 2021 18:45:33
User entered '1'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:45:47
User entered 'Jan 1995'	System	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:45:47
User entered '1995'	System	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:45:33
User entered empty.	System	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:45:33
User entered empty.	System	16 Apr 2021 18:42:25

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
Query 'Per previous source records, medical history captured from subject at start of study, Cesarean section occurred 1997. This is captured already at beginning of medical history items. Please review and remove duplicate; update date as necessary in previous entry (1995 or 1997 correct as is). Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:56:30
User opened query 'Per previous source records, medical history captured from subject at start of study, Cesarean section occurred 1997. This is captured already at beginning of medical history items. Please review and remove duplicate; update date as necessary in previous entry (1995 or 1997 correct as is). Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Cesarean section, LLT: Cesarean section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 18:44:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:44:04
Data point term sent to Coder	System	16 Apr 2021 18:43:19
User entered 'caesarean section'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1995'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1995'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:56:38
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1995'	System	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1995'	System	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1995'	System	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1995'	System	16 Apr 2021 18:43:04

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:45:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:45:04
Data point term sent to Coder	System	16 Apr 2021 18:44:20
User entered 'tubal ligation'	lynn yauch (b) (4)	16 Apr 2021 18:43:29
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1997'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1997'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:43:29

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Joint dislocation reduction, LLT: Reduction of dislocated knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:08:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:08:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	19 Apr 2021 13:13:19
Data point term sent to Coder	System	16 Apr 2021 18:44:20
User entered 'reconstruction of dislocated patella right'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1997'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1997'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:27:34
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1997'	System	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1997'	System	16 Apr 2021 18:44:03

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 08:25:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 08:25:34
Data point term sent to Coder	System	16 Apr 2021 18:48:24
User entered 'schizo affective disorder'	lynn yauch (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1993'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1993'	System	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1993'	System	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:48:23

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User closed query 'Per MM, please review and update the term to reflect the underlying etiology if known.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 06:18:15
Query 'Per MM, please review and update the term to lynn yauch reflect the underlying etiology if known.' answered with 'term is recorded verbatim from medical records, no additional information is known ' (Site from DM).	(b) (4)	26 Apr 2021 19:11:33
User opened query 'Per MM, please review and update the term to reflect the underlying etiology if known.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 15:52:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0.	Coder Import (b) (4)	16 Apr 2021 18:50:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Apr 2021 18:50:55
Data point term sent to Coder	System	16 Apr 2021 18:50:29
User entered 'abnormal uterine bleeding'	lynn yauch (b) (4)	16 Apr 2021 18:50:00
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	16 Apr 2021 18:50:19
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	16 Apr 2021 18:50:00
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 18:50:00
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:50:19
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	16 Apr 2021 18:50:00
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
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	16 Apr 2021 18:50:19
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 18:50:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Apr 2021 18:50:00
	lynn yauch (b) (4)	16 Apr 2021 18:50:00
	(b) (4)	

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Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:57
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:00

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Neisseria infections, PT: Gonococcal infection, LLT: Gonococcal infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 18:53:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:53:42
Data point term sent to Coder	System	16 Apr 2021 18:51:34
User entered 'gonococcal infection'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:53
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:50:47

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Apr 2021 18:53:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:53:02
Data point term sent to Coder	System	16 Apr 2021 18:51:34
User entered 'herpes simplex'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

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Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:42
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:12

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Infections and infestations, HLGT: Chlamydial infectious disorders, HLT: Chlamydial infections, PT: Chlamydial infection, LLT: Chlamydial infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Apr 2021 18:53:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:53:02
Data point term sent to Coder	System	16 Apr 2021 18:51:34
User entered 'chlamydia'	lynn yauch (b) (4)	16 Apr 2021 18:51:32
	(b) (4)	

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Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:47
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:51:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 18:53:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:53:03
Data point term sent to Coder	System	16 Apr 2021 18:52:35
User entered 'knee surgery right'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1995'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'un UNK 1995'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:25
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1995'	System	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1995'	System	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered 'Jan 1995'	System	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered '1995'	System	16 Apr 2021 18:52:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:55:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 18:55:06
Data point term sent to Coder	System	16 Apr 2021 18:53:36
User entered 'alcohol abuse'	lynn yauch (b) (4)	16 Apr 2021 18:53:32
	(b) (4)	

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Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'l'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:16
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	16 Apr 2021 18:53:32

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Peripheral edema - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 18:50:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 18:50:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:46:01
User closed query 'Per Investigator notes within source, peripheral edema noted, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:45:36
Data point term sent to Coder	System	21 Apr 2021 17:28:52
Query 'Per Investigator notes within source, peripheral edema noted, please review and reconcile.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 17:28:47
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 17:28:31
Coding entries removed.	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 17:28:31
Signature has been broken.	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 17:28:31
User entered 'Peripheral EDEMA' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 17:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User opened query 'Per Investigator notes within source, peripheral edema noted, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:26:52
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Edema - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 21:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 21:29:46
Data point term sent to Coder	System	19 Apr 2021 21:29:05

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

Condition

Audit	User	Time (GMT)
Coding entries removed.	lynn yauch (b) (4)	19 Apr 2021 21:28:34
	(b) (4)	
User entered 'edema' reason for change: Data Entry Error	lynn yauch (b) (4)	19 Apr 2021 21:28:34
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:26:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:26:43
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 21:26:03
User entered 'chronic anemia'	lynn yauch (b) (4)	19 Apr 2021 21:25:08
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 21:25:41
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	19 Apr 2021 21:25:41
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 21:25:08
User entered 'un UNK 2021'	System	19 Apr 2021 21:25:08
	lynn yauch (b) (4)	19 Apr 2021 21:25:08
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User entered '1' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	19 Apr 2021 21:25:41
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	19 Apr 2021 21:25:08
	(b) (4)	

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:28:05
User signature succeeded.	Michele Reynolds (b) (4)	20 Apr 2021 14:38:46
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	19 Apr 2021 21:25:41
User entered 'Jan 2021'	System	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	19 Apr 2021 21:25:41
User entered '2021'	System	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 10:23:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:06:53
User entered empty.	System	19 Apr 2021 21:25:08

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered '11:44'	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered '3 Sep 2020 11:44'	System	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered '170.0' cm	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34
DataPoint set to visible.	(b) (4) System	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered '133.5' kg	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34
DataPoint set to visible.	(b) (4) System	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered '46.19377'	System	09 Sep 2020 14:36:34
DataPoint set to visible.	System	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'kg/m2'	System	09 Sep 2020 14:36:34
DataPoint set to visible.	System	03 Sep 2020 19:03:03

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'bpm'	System	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'breaths/min'	System	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'mmHg'	System	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:23
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User entered 'mmHg'	System	09 Sep 2020 14:36:34

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 02:38:00

US3922080

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 02:38:00

US3922080

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:16
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:36:43

US3922080

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:16
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:36:43

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:12:41
User closed query 'Please note that patient has had a hysterectomy (un Sep 2014), not post menopausal. Please review and revise if needed in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:12:29
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	06 Nov 2020 19:48:06
Query 'Please note that patient has had a hysterectomy (un Sep 2014), not post menopausal. Please review and revise if needed in EDC. Thank you.' answered with 'corrected ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:46:06
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	06 Nov 2020 19:45:58
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:45:58
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User opened query 'Please note that patient has had a hysterectomy (un Sep 2014), not post menopausal. Please review and revise if needed in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 17:05:20
User closed query 'Per DM CLR: Re-Query: Per response as "updated" is noted, however, there is no Post-menopausal condition recorded on MH eCRF. Please consider recording this condition in MH form.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:40:32

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

If No, what is the reason?

Audit	User	Time (GMT)
Query 'Per DM CLR: Re-Query: Per response as "updated" is noted, however, there is no Post-menopausal condition recorded on MH eCRF. Please consider recording this condition in MH form.' answered with 'updated MH eCRF per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	21 Oct 2020 13:04:36
User opened query 'Per DM CLR: Re-Query: Per response as "updated" is noted, however, there is no Post-menopausal condition recorded on MH eCRF. Please consider recording this condition in MH form.' (Site from DM).	(b) (4), (b) (6) (b) (4)	20 Oct 2020 04:49:33
User closed query 'Per DM CLR re-query: Response noted. However, Post-Menopausal is recorded in MH. Please confirm if subject is Surgically sterile or Post-menopausal and update this form and MH form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	20 Oct 2020 04:49:33
Query 'Per DM CLR re-query: Response noted. However, Post-Menopausal is recorded in MH. Please confirm if subject is Surgically sterile or Post-menopausal and update this form and MH form as appropriate. Thank you.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	15 Oct 2020 13:53:35
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	15 Oct 2020 13:53:26
User opened query 'Per DM CLR re-query: Response noted. However, Post-Menopausal is recorded in MH. Please confirm if subject is Surgically sterile or Post-menopausal and update this form and MH form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	07 Oct 2020 11:34:30
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	07 Oct 2020 11:34:30

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

If No, what is the reason?

Audit	User	Time (GMT)
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'MH updated' (Site from DM).	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:43:19
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	30 Sep 2020 07:11:00
User entered 'Surgically sterile (SURGICALLY STERILE)'	Patrick Brooks (b) (4) (b) (4)	09 Sep 2020 14:37:21

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:12:38
User closed query 'Please note that patient had a hysterectomy; not post-menopausal. Please ensure to document date of procedure (un Sep 2014). Thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:12:33
Query 'Please note that patient had a hysterectomy; not post-menopausal. Please ensure to document date of procedure (un Sep 2014). Thank you.' answered with 'corrected ' (Site from CRA).	Lorine Cook (b) (4)	06 Nov 2020 19:46:12
User entered 'un Sep 2014' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 19:45:58
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User opened query 'Please note that patient had a hysterectomy; not post-menopausal. Please ensure to document date of procedure (un Sep 2014). Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 17:05:59
User entered empty; reason for change Data Entry Error	Pauline Jackson (b) (4)	15 Oct 2020 13:53:26
User entered 'UN Sep 2014'	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:12:36
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	06 Nov 2020 19:48:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered 'un Sep 2014' reason for change: Data Entry Error	Pauline Jackson (b) (4)	15 Oct 2020 13:53:26
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

US3922080

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:23:52

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:01
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:37:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

US3922080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

US3922080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

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 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered 'I'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

US3922080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

US3922080

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User entered '0'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:23:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:38:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:03:53
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:38:16

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:35
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:35

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:35
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:35

US3922080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:35
User entered 'Clinic (Clinic)'	Patrick Brooks (b) (4)	09 Sep 2020 14:38:35

US3922080

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'VISIT1'	System	09 Sep 2020 14:38:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:04:30

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered '145382'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:04:30

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:06:53
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:40:59
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:37:21
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:04:30

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

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)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 21:37:21

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

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)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 21:37:21

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Cristina Puig (b) (4)	04 Sep 2020 21:40:59
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 21:37:21

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 21:37:21

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 21:37:21

US3922080

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:23:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:06:53
User entered 'No (N)'	lynn yauch (b) (4)	01 Oct 2020 17:28:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:13:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:13:01

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Pre-Dose (PREDOSE)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '11:44'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '3 Sep 2020 11:44'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '98.7' F	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered 'Oral (Oral)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '69'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'bpm'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '16'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'breaths/min'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '137'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '95'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:23:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Post-Dose (POSTDOSE)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '14:19'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '3 Sep 2020 14:19'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered missing code ND - Not Done.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '79'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'bpm'	System	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '17'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'breaths/min'	System	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:09:28
User entered '140'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:09:28
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:02:25
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI' (Site from System).	Lorine Cook (b) (4)	10 Sep 2020 15:45:23
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Sep 2020 14:41:03
User entered '104'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	09 Sep 2020 14:41:03

US3922080

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:23
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:41:42

US3922080

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:23
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:41:42

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered 'Yes (Y)'	Chana Hines (b) (4)	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered empty.	Chana Hines (b) (4)	03 Sep 2020 19:11:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

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)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered empty.	Chana Hines (b) (4)	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:11:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered '3 Sep 2020'	Chana Hines (b) (4)	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered '13:44'	Chana Hines (b) (4)	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '3 Sep 2020 13:44'	System	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered 'Left Arm (LEFT ARM)'	Chana Hines (b) (4)	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:08:03
User entered 'ONCE'	System	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:11:17

US3922080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:21
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:25

US3922080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:21
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:25

US3922080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:21
User entered '12:24'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:25

US3922080

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '3 Sep 2020 12:24'	System	09 Sep 2020 14:42:25

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:23:52

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:49
User entered '3 Sep 2020'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:49
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:49
User entered '12:47'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '3 Sep 2020 12:47'	System	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:49
User entered 'No (N)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:49
User entered empty.	Patrick Brooks (b) (4)	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	09 Sep 2020 14:42:42

US3922080

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:07:53
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	09 Sep 2020 14:42:53

US3922080

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	09 Sep 2020 14:42:53

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:17:10', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '253145f8-89f4-4faa-b2d9-0629be060f1e'	System	03 Sep 2020 19:18:35
User entered 'Yes (Y)'	System	03 Sep 2020 19:18:35

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:11', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '253145f8-89f4-4faa-b2d9-0629be060f1e'	System	03 Sep 2020 19:18:35
User entered '98.1'	System	03 Sep 2020 19:18:35

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '253145f8-89f4-4faa-b2d9-0629be060f1e'	System	03 Sep 2020 19:18:35
User entered 'No (N)'	System	03 Sep 2020 19:18:35

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:30', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '253145f8-89f4-4faa-b2d9-0629be060f1e'	System	03 Sep 2020 19:18:35
User entered '03 Sep 2020 14:18'	System	03 Sep 2020 19:18:35

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 14:04'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 16:34'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'ac8fbbaa-b6d6-4f1b-8193-a5f5768171cc'	System	04 Sep 2020 02:26:30
User entered 'No (N)'	System	04 Sep 2020 02:26:30

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:24', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'ac8fbbaa-b6d6-4f1b-8193-a5f5768171cc'	System	04 Sep 2020 02:26:30
User entered 'No (N)'	System	04 Sep 2020 02:26:30

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'ac8fbbaa-b6d6-4f1b-8193-a5f5768171cc'	System	04 Sep 2020 02:26:30
User entered '03 Sep 2020 21:26'	System	04 Sep 2020 02:26:30

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 17:29'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 2'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:02:40', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '63891720-63d7-4f05-ae6b-c37b77df3698'	System	04 Sep 2020 21:03:02
User entered 'Yes (Y)'	System	04 Sep 2020 21:03:02

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-04T16:02:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '63891720-63d7-4f05-ae6b-c37b77df3698'	System	04 Sep 2020 21:03:02
User entered '96.1'	System	04 Sep 2020 21:03:02

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:02:52', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '63891720-63d7-4f05-ae6b-c37b77df3698'	System	04 Sep 2020 21:03:02
User entered 'No (N)'	System	04 Sep 2020 21:03:02

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:02:57', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '63891720-63d7-4f05-ae6b-c37b77df3698'	System	04 Sep 2020 21:03:02
User entered '04 Sep 2020 16:02'	System	04 Sep 2020 21:03:02

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 3'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-05T18:08:28', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'c8c6bb42-5219-481e-9dc3-67ecb940bf5e'	System	05 Sep 2020 23:08:52
User entered 'Yes (Y)'	System	05 Sep 2020 23:08:52

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-05T18:08:35', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'c8c6bb42-5219-481e-9dc3-67ecb940bf5e'	System	05 Sep 2020 23:08:52
User entered '97.7'	System	05 Sep 2020 23:08:52

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:08:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'c8c6bb42-5219-481e-9dc3-67ecb940bf5e'	System	05 Sep 2020 23:08:52
User entered 'No (N)'	System	05 Sep 2020 23:08:52

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:08:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'c8c6bb42-5219-481e-9dc3-67ecb940bf5e'	System	05 Sep 2020 23:08:52
User entered '05 Sep 2020 18:08'	System	05 Sep 2020 23:08:52

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 4'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:41:30', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '7f4dc7a4-bb15-4707-a066-0179e40acdef'	System	06 Sep 2020 23:42:21
User entered 'Yes (Y)'	System	06 Sep 2020 23:42:21

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:07', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '7f4dc7a4-bb15-4707-a066-0179e40acdef'	System	06 Sep 2020 23:42:21
User entered '98.4'	System	06 Sep 2020 23:42:21

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:13', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '7f4dc7a4-bb15-4707-a066-0179e40acdef'	System	06 Sep 2020 23:42:21
User entered 'No (N)'	System	06 Sep 2020 23:42:21

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:16', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '7f4dc7a4-bb15-4707-a066-0179e40acdef'	System	06 Sep 2020 23:42:21
User entered '06 Sep 2020 18:42'	System	06 Sep 2020 23:42:21

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 5'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T08:46:07', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'fbc9f2a5-56ba-4c08-a0db-13d0f15faf4a'	System	08 Sep 2020 13:46:25
User entered 'Yes (Y)'	System	08 Sep 2020 13:46:25

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T08:46:13', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'fbc9f2a5-56ba-4c08-a0db-13d0f15faf4a'	System	08 Sep 2020 13:46:25
User entered '98.2'	System	08 Sep 2020 13:46:25

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'fbc9f2a5-56ba-4c08-a0db-13d0f15faf4a'	System	08 Sep 2020 13:46:25
User entered 'No (N)'	System	08 Sep 2020 13:46:25

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T08:46:19', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'fbc9f2a5-56ba-4c08-a0db-13d0f15faf4a'	System	08 Sep 2020 13:46:25
User entered '08 Sep 2020 08:46'	System	08 Sep 2020 13:46:25

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 6'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:19', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '37567032-7de0-4174-9847-c5524a48230d'	System	08 Sep 2020 23:04:37
User entered 'Yes (Y)'	System	08 Sep 2020 23:04:37

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:24', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '37567032-7de0-4174-9847-c5524a48230d' User entered '98.7'	System	08 Sep 2020 23:04:37
	System	08 Sep 2020 23:04:37

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:28', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '37567032-7de0-4174-9847-c5524a48230d'	System	08 Sep 2020 23:04:37
User entered 'No (N)'	System	08 Sep 2020 23:04:37

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:30', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '37567032-7de0-4174-9847-c5524a48230d'	System	08 Sep 2020 23:04:37
User entered '08 Sep 2020 18:04'	System	08 Sep 2020 23:04:37

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 7'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:01', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0e9c9cf-5128-4df2-b2b2-be4d62d8ac50'	System	09 Sep 2020 21:13:16
User entered 'Yes (Y)'	System	09 Sep 2020 21:13:16

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:05', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0e9c9cf-5128-4df2-b2b2-be4d62d8ac50'	System	09 Sep 2020 21:13:16
User entered '98.3'	System	09 Sep 2020 21:13:16

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:08', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0e9c9cf-5128-4df2-b2b2-be4d62d8ac50'	System	09 Sep 2020 21:13:16
User entered 'No (N)'	System	09 Sep 2020 21:13:16

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:10', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0e9c9cf-5128-4df2-b2b2-be4d62d8ac50'	System	09 Sep 2020 21:13:16
User entered '09 Sep 2020 16:13'	System	09 Sep 2020 21:13:16

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:40', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '2c119266-688a-412e-b5c6-12cdff033b5a'	System	03 Sep 2020 19:19:03
User entered 'None (1)'	System	03 Sep 2020 19:19:03

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:45', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '2c119266-688a-412e-b5c6-12cdff033b5a'	System	03 Sep 2020 19:19:03
User entered 'No (N)'	System	03 Sep 2020 19:19:03

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '2c119266-688a-412e-b5c6-12cdff033b5a'	System	03 Sep 2020 19:19:03
User entered 'No (N)'	System	03 Sep 2020 19:19:03

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:18:56', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '2c119266-688a-412e-b5c6-12cdff033b5a'	System	03 Sep 2020 19:19:03
User entered 'None (1)'	System	03 Sep 2020 19:19:03

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '2c119266-688a-412e-b5c6-12cdff033b5a'	System	03 Sep 2020 19:19:03
User entered '03 Sep 2020 14:19'	System	03 Sep 2020 19:19:03

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 14:04'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 16:34'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:36', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'cc08f446-1740-40ba-9844-5368fe76126a'	System	04 Sep 2020 02:26:52
User entered 'None (1)'	System	04 Sep 2020 02:26:52

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'cc08f446-1740-40ba-9844-5368fe76126a'	System	04 Sep 2020 02:26:52
User entered 'No (N)'	System	04 Sep 2020 02:26:52

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:42', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'cc08f446-1740-40ba-9844-5368fe76126a'	System	04 Sep 2020 02:26:52
User entered 'No (N)'	System	04 Sep 2020 02:26:52

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:45', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'cc08f446-1740-40ba-9844-5368fe76126a'	System	04 Sep 2020 02:26:52
User entered 'None (1)'	System	04 Sep 2020 02:26:52

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:26:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'cc08f446-1740-40ba-9844-5368fe76126a'	System	04 Sep 2020 02:26:52
User entered '03 Sep 2020 21:26'	System	04 Sep 2020 02:26:52

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 17:29'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 2'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:01', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0f9a489-49de-4c77-87e7-59bfbf315392'	System	04 Sep 2020 21:03:15
User entered 'None (1)'	System	04 Sep 2020 21:03:15

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:03', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0f9a489-49de-4c77-87e7-59bfbf315392'	System	04 Sep 2020 21:03:15
User entered 'No (N)'	System	04 Sep 2020 21:03:15

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:06', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0f9a489-49de-4c77-87e7-59bfbf315392'	System	04 Sep 2020 21:03:15
User entered 'No (N)'	System	04 Sep 2020 21:03:15

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:09', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0f9a489-49de-4c77-87e7-59bfbf315392'	System	04 Sep 2020 21:03:15
User entered 'None (1)'	System	04 Sep 2020 21:03:15

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:11', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a0f9a489-49de-4c77-87e7-59bfbf315392'	System	04 Sep 2020 21:03:15
User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:03:15

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 3'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:08:57', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '66545e59-7bfa-4102-9506-b946e468d612'	System	05 Sep 2020 23:09:23
User entered 'None (1)'	System	05 Sep 2020 23:09:23

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:11', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '66545e59-7bfa-4102-9506-b946e468d612'	System	05 Sep 2020 23:09:23
User entered 'No (N)'	System	05 Sep 2020 23:09:23

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:14', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '66545e59-7bfa-4102-9506-b946e468d612'	System	05 Sep 2020 23:09:23
User entered 'No (N)'	System	05 Sep 2020 23:09:23

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '66545e59-7bfa-4102-9506-b946e468d612'	System	05 Sep 2020 23:09:23
User entered 'None (1)'	System	05 Sep 2020 23:09:23

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '66545e59-7bfa-4102-9506-b946e468d612'	System	05 Sep 2020 23:09:23
User entered '05 Sep 2020 18:09'	System	05 Sep 2020 23:09:23

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 4'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:21', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd1af1a62-1c89-4308-b20b-52f250247ebc'	System	06 Sep 2020 23:42:38
User entered 'None (1)'	System	06 Sep 2020 23:42:38

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:25', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd1af1a62-1c89-4308-b20b-52f250247ebc'	System	06 Sep 2020 23:42:38
User entered 'No (N)'	System	06 Sep 2020 23:42:38

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd1af1a62-1c89-4308-b20b-52f250247ebc'	System	06 Sep 2020 23:42:38
User entered 'No (N)'	System	06 Sep 2020 23:42:38

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:29', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd1af1a62-1c89-4308-b20b-52f250247ebc'	System	06 Sep 2020 23:42:38
User entered 'None (1)'	System	06 Sep 2020 23:42:38

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:32', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd1af1a62-1c89-4308-b20b-52f250247ebc'	System	06 Sep 2020 23:42:38
User entered '06 Sep 2020 18:42'	System	06 Sep 2020 23:42:38

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 5'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:24', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '1a01319c-068b-4ce3-b316-b2a2d097ffed'	System	08 Sep 2020 13:46:37
User entered 'None (1)'	System	08 Sep 2020 13:46:37

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '1a01319c-068b-4ce3-b316-b2a2d097ffed'	System	08 Sep 2020 13:46:37
User entered 'No (N)'	System	08 Sep 2020 13:46:37

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:29', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '1a01319c-068b-4ce3-b316-b2a2d097ffed'	System	08 Sep 2020 13:46:37
User entered 'No (N)'	System	08 Sep 2020 13:46:37

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:32', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '1a01319c-068b-4ce3-b316-b2a2d097ffed'	System	08 Sep 2020 13:46:37
User entered 'None (1)'	System	08 Sep 2020 13:46:37

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:34', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '1a01319c-068b-4ce3-b316-b2a2d097ffed'	System	08 Sep 2020 13:46:37
User entered '08 Sep 2020 08:46'	System	08 Sep 2020 13:46:37

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 6'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:35', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '32ece398-a698-473c-8e52-2948e3acbb13'	System	08 Sep 2020 23:04:48
User entered 'None (1)'	System	08 Sep 2020 23:04:48

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '32ece398-a698-473c-8e52-2948e3acbb13'	System	08 Sep 2020 23:04:48
User entered 'No (N)'	System	08 Sep 2020 23:04:48

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:41', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '32ece398-a698-473c-8e52-2948e3acbb13'	System	08 Sep 2020 23:04:48
User entered 'No (N)'	System	08 Sep 2020 23:04:48

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:43', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '32ece398-a698-473c-8e52-2948e3acbb13'	System	08 Sep 2020 23:04:48
User entered 'None (1)'	System	08 Sep 2020 23:04:48

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T18:04:45', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '32ece398-a698-473c-8e52-2948e3acbb13'	System	08 Sep 2020 23:04:48
User entered '08 Sep 2020 18:04'	System	08 Sep 2020 23:04:48

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 7'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:15', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b107ccf5-cf01-4836-8001-2261945c0e53'	System	09 Sep 2020 21:13:31
User entered 'None (1)'	System	09 Sep 2020 21:13:31

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-09T16:13:18', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b107ccf5-cf01-4836-8001-2261945c0e53'	System	09 Sep 2020 21:13:31
User entered 'No (N)'	System	09 Sep 2020 21:13:31

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b107ccf5-cf01-4836-8001-2261945c0e53'	System	09 Sep 2020 21:13:31
User entered 'No (N)'	System	09 Sep 2020 21:13:31

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:23', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b107ccf5-cf01-4836-8001-2261945c0e53'	System	09 Sep 2020 21:13:31
User entered 'None (1)'	System	09 Sep 2020 21:13:31

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:28', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b107ccf5-cf01-4836-8001-2261945c0e53'	System	09 Sep 2020 21:13:31
User entered '09 Sep 2020 16:13'	System	09 Sep 2020 21:13:31

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:09', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:13', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T14:19:23', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'None (0)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:34', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered 'No (N)'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T14:19:37', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3188a679-3f1f-437a-bf5c-8faad923313e'	System	03 Sep 2020 19:19:39
User entered '03 Sep 2020 14:19'	System	03 Sep 2020 19:19:39

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 14:04'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 16:34'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:26:59', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:27:02', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:27:05', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:27:07', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:27:09', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:27:11', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'None (0)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-03T21:27:14', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered 'No (N)'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-03T21:27:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '30e6efed-0701-4d5e-a4f8-ef3a5e2e9673'	System	04 Sep 2020 02:27:23
User entered '03 Sep 2020 21:27'	System	04 Sep 2020 02:27:23

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '03 Sep 2020 17:29'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 2'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:15', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:18', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:22', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:24', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'None (0)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered 'No (N)'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-04T16:03:30', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b2feb84f-777c-4372-8528-80996e9e3154'	System	04 Sep 2020 21:03:33
User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:03:33

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 3'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:29', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:32', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:34', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:36', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:38', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'None (0)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:44', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered 'No (N)'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-05T18:09:46', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'e01af684-00e9-4cbf-bd03-531594d67716'	System	05 Sep 2020 23:09:52
User entered '05 Sep 2020 18:09'	System	05 Sep 2020 23:09:52

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 4'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:41', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:44', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:46', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:47', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:49', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'None (0)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:53', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered 'No (N)'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-06T18:42:55', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93aa5e66-1468-4236-be34-3bbce6a6eb83'	System	06 Sep 2020 23:43:04
User entered '06 Sep 2020 18:42'	System	06 Sep 2020 23:43:04

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 5'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T08:46:38', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:42', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:44', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:46', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-08T08:46:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'None (0)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:50', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered 'No (N)'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T08:46:52', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '191f76d4-e44d-4271-95ba-164a5f933621'	System	08 Sep 2020 13:46:54
User entered '08 Sep 2020 08:46'	System	08 Sep 2020 13:46:54

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 6'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:49', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:52', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:53', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:55', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:57', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:04:59', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'None (0)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:05:02', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered 'No (N)'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-08T18:05:15', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'a80511d5-749a-4c47-bd2b-dab509189f97'	System	08 Sep 2020 23:05:19
User entered '08 Sep 2020 18:05'	System	08 Sep 2020 23:05:19

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 7'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:32', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:33', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:35', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:37', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:38', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:40', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'None (0)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

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 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbdd8f1859d38d5)', Time: '2020-09-09T16:13:42', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered 'No (N)'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbedd8f1859d38d5)', Time: '2020-09-09T16:13:45', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'd11ce957-fc76-42cb-8f3f-7ed4246ad187'	System	09 Sep 2020 21:13:49
User entered '09 Sep 2020 16:13'	System	09 Sep 2020 21:13:49

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:11:17

US3922080

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:23:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:37
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:11:17

US3922080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:53
User entered 'Yes (Y)'	Lorine Cook (b) (4)	10 Sep 2020 23:20:57

US3922080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:53
User entered '10 Sep 2020'	Lorine Cook (b) (4)	10 Sep 2020 23:20:57

US3922080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:53
User entered 'Contact Made (CONTACT MADE)'	Lorine Cook (b) (4)	10 Sep 2020 23:20:57

US3922080

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:53
User entered empty.	Lorine Cook (b) (4)	10 Sep 2020 23:20:57

US3922080

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:10:58
User entered 'Yes (Y)'	Lorine Cook (b) (4)	10 Sep 2020 23:21:05

US3922080

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	10 Sep 2020 23:21:05

US3922080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:59
User entered 'Yes (Y)'	Cristina Puig (b) (4)	17 Sep 2020 23:07:38

US3922080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:59
User entered '17 Sep 2020'	Cristina Puig (b) (4)	17 Sep 2020 23:07:38

US3922080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:59
User entered 'Contact Made (CONTACT MADE)'	Cristina Puig (b) (4)	17 Sep 2020 23:07:38

US3922080

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:59
User entered empty.	Cristina Puig (b) (4)	17 Sep 2020 23:07:38

US3922080

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:13:03
User entered 'Yes (Y)'	Cristina Puig (b) (4)	17 Sep 2020 23:07:43

US3922080

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	17 Sep 2020 23:07:43

US3922080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:21
User entered 'Yes (Y)'	Jacklyn Newton (b) (4)	24 Sep 2020 21:42:03

US3922080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:21
User entered '24 Sep 2020'	Jacklyn Newton (b) (4)	24 Sep 2020 21:42:03

US3922080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:21
User entered 'Contact Made (CONTACT MADE)'	Jacklyn Newton (b) (4)	24 Sep 2020 21:42:03

US3922080

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:21
User entered empty.	Jacklyn Newton (b) (4)	24 Sep 2020 21:42:03

US3922080

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:29
User entered 'Yes (Y)'	Jacklyn Newton (b) (4)	24 Sep 2020 21:42:07

US3922080

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	24 Sep 2020 21:42:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:58
User closed query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:55:25
Query 'Per CDM: Please complete all forms for this visit. Thank you.' answered with 'Updated' (Site from DM).	Pauline Jackson (b) (4)	15 Oct 2020 13:46:23
User opened query 'Per CDM: Please complete all forms for this visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:16:06
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:56:04

US3922080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:56:58
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:26:26
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'date added' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	26 Oct 2020 19:12:14
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:31:47
User entered '02 Oct 2020'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:56:04

US3922080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:56:58
User entered 'Clinic (Clinic)'	lynn yauch (b) (4)	05 Oct 2020 16:56:04

US3922080

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'VISIT2'	System	05 Oct 2020 16:56:04

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Pre-Dose (PREDOSE)'	lynn yauch (b) (4)	05 Oct 2020 16:57:46
	(b) (4)	

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '02 Oct 2020'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '12:00'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '02 Oct 2020 12:00'	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '96.9' F	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered 'Oral (Oral)'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '82'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'bpm'	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '18'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'breaths/min'	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '139'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered '102'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Post-Dose (POSTDOSE)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:47:36
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:57:46

US3922080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:57:48
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:56:16

US3922080

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:57:48
User entered '02 Oct 2020'	lynn yauch (b) (4)	05 Oct 2020 16:56:16

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
User closed query 'Please note that due to subject not receiving 2nd dose, eCRF completion guidelines require that Dosing Discontinuation page needs to be entered within EDC for subject (unable to query page currently).' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:58:06
Query 'Please note that due to subject not receiving 2nd dose, eCRF completion guidelines require that Dosing Discontinuation page needs to be entered within EDC for subject (unable to query page currently).' answered with 'form has been updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Feb 2021 13:37:50
User opened query 'Please note that due to subject not receiving 2nd dose, eCRF completion guidelines require that Dosing Discontinuation page needs to be entered within EDC for subject (unable to query page currently).' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:05:59
Query 'Please note that due to subject not receiving 2nd dose, eCRF completion guidelines require that patient be treatment discontinued in IRT and please update Dosing Discontinuation page in end of study folder. Please follow eCRF completion guidelines for proper completion of Dosing Discontinuation page.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:05:16
User opened query 'Please note that due to subject not receiving 2nd dose, eCRF completion guidelines require that patient be treatment discontinued in IRT and please update Dosing Discontinuation page in end of study folder. Please follow eCRF completion guidelines for proper completion of Dosing Discontinuation page.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:00:14
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

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)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 20:58:21
User entered empty.	System	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:23:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	05 Oct 2020 16:56:53

US3922080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:05
User entered 'No (N)'	Pauline Jackson (b) (4)	15 Oct 2020 13:45:39

US3922080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:15
User entered '02 Oct 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:05
User entered empty.	Pauline Jackson (b) (4)	15 Oct 2020 13:45:39

US3922080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:15
User entered '13:30' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:05
User entered empty.	Pauline Jackson (b) (4)	15 Oct 2020 13:45:39

US3922080

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '02 Oct 2020 13:30'	System	26 Oct 2020 19:11:05
User entered empty.	System	15 Oct 2020 13:45:39

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:23:52

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:23
User entered '2 Oct 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:39
User entered empty.	Pauline Jackson (b) (4)	15 Oct 2020 13:46:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Pauline Jackson (b) (4) (b) (4)	15 Oct 2020 13:46:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:39
User entered 'No (N)'	Pauline Jackson (b) (4)	15 Oct 2020 13:46:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:23
User entered '13:42' reason for change: Data Entry Error	Pauline Jackson (b) (4)	26 Oct 2020 19:11:39
User entered empty.	Pauline Jackson (b) (4)	15 Oct 2020 13:46:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '2 Oct 2020 13:42'	System	26 Oct 2020 19:11:39
User entered empty.	System	15 Oct 2020 13:46:07

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Pauline Jackson (b) (4) (b) (4)	15 Oct 2020 13:46:14

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:23
User entered 'No (N)'	Pauline Jackson (b) (4)	15 Oct 2020 13:46:14

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:23
User entered empty.	Pauline Jackson (b) (4)	15 Oct 2020 13:46:14

US3922080

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered empty.	System	15 Oct 2020 13:46:14

US3922080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:06:29
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:57:02

US3922080

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	05 Oct 2020 16:57:02

US3922080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:08:00
User entered 'No (N)'	lynn yauch (b) (4)	28 Oct 2020 15:56:37

US3922080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:08:00
User entered empty.	lynn yauch (b) (4)	28 Oct 2020 15:56:37

US3922080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:08:00
User entered empty.	lynn yauch (b) (4)	28 Oct 2020 15:56:37

US3922080

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:08:00
User entered empty.	lynn yauch (b) (4)	28 Oct 2020 15:56:37

US3922080

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:08:04
User entered 'Yes (Y)'	lynn yauch (b) (4)	28 Oct 2020 15:56:45

US3922080

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	28 Oct 2020 15:56:45

US3922080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:16:15
User closed query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 29OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:14:35
Query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 29OCT2020, per GCL. Please clarify and update as appropriate. ' answered with 'Visit 3 is updated' (Site from DM).	lynn yauch (b) (4) (b) (4)	12 Nov 2020 16:14:06
User opened query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 29OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 19:07:06
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	28 Oct 2020 15:56:55

US3922080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:15
User entered empty.	lynn yauch (b) (4)	28 Oct 2020 15:56:55

US3922080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:15
User entered empty.	lynn yauch (b) (4)	28 Oct 2020 15:56:55

US3922080

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:15
User entered 'safety call was missed, this will be a protocol deviation.' reason for change: Data Entry Error	lynn yauch (b) (4)	11 Nov 2020 13:52:05
User entered empty.	(b) (4)	28 Oct 2020 15:56:55

US3922080

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:19
User entered 'Yes (Y)'	lynn yauch (b) (4)	28 Oct 2020 15:57:01

US3922080

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	28 Oct 2020 15:57:01

US3922080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:54
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 13:48:09

US3922080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:54
User entered '23 Oct 2020'	lynn yauch (b) (4)	11 Nov 2020 13:48:09

US3922080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:54
User entered 'Contact Not Made (CONTACT NOT MADE)'	lynn yauch (b) (4)	11 Nov 2020 13:48:09

US3922080

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:54
User entered 'site attempted to contact subject on 23OCT2020, 27OCT2020 and 28OCT2020, messages left on voicemail, email sent, calls not returned.'	lynn yauch (b) (4)	11 Nov 2020 13:48:09

US3922080

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:16:59
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 13:48:15

US3922080

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	11 Nov 2020 13:48:15

US3922080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:20:21
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 13:56:37

US3922080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:20:21
User entered '29 Oct 2020'	lynn yauch (b) (4)	11 Nov 2020 13:56:37

US3922080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:20:21
User entered 'Clinic (Clinic)'	lynn yauch (b) (4)	11 Nov 2020 13:56:37

US3922080

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:23:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'VISIT3'	System	11 Nov 2020 13:56:37

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '29 Oct 2020'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '09:03'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '29 Oct 2020 09:03'	System	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '98.1' F	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered 'Oral (Oral)'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered empty.	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '82'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'bpm'	System	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '17'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'breaths/min'	System	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:22:40
User entered '138'	lynn yauch (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:22:40
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 06:54:06
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI review' (Site from System).	lynn yauch (b) (4) (b) (4)	12 Nov 2020 16:11:26
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Nov 2020 13:59:01
User entered '109'	lynn yauch (b) (4) (b) (4)	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'mmHg'	System	11 Nov 2020 13:59:01

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 08:50:58

US3922080

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:23:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 08:50:58

US3922080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:20:56
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 14:01:17

US3922080

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:23:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:20:56
User entered '29 Oct 2020'	lynn yauch (b) (4)	11 Nov 2020 14:01:17

US3922080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:21:11
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 14:02:06

US3922080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:21:11
User entered '29 Oct 2020'	lynn yauch (b) (4)	11 Nov 2020 14:02:06

US3922080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:21:11
User entered '09:08'	lynn yauch (b) (4)	11 Nov 2020 14:02:06

US3922080

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:23:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered '29 Oct 2020 09:08'	System	11 Nov 2020 14:02:06

US3922080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:21:27
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Nov 2020 14:02:11

US3922080

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	11 Nov 2020 14:02:11

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 64'	System	03 Sep 2020 19:11:17

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Have you been exposed to someone with 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

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[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

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[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:11:17

US3922080

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:11:17

US3922080

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Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 71'	System	03 Sep 2020 19:11:17

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Folder: Safety Follow Up Diary (1)

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[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Have you been exposed to someone with 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
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[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Nausea](#)

Audit	User	Time (GMT)
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
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[Please 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)
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[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)
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Audit	User	Time (GMT)
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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:11:17

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:11:17

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered 'Day 78'	System	03 Sep 2020 19:11:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
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Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

US3922080

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Please 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)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:11:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:27
DataPoint activated (WR#5356875)	System	16 Apr 2021 21:25:28
DataPoint Inactivated.	System	13 Apr 2021 21:39:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:21:24
Data entry locked.	System	03 Sep 2020 19:11:17
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:11:17

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:21:24

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-16T12:25:41', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93f85072-c635-4249-8e5b-feca4faef08e' User entered 'No (N)'	System	16 Dec 2020 18:25:50
	System	16 Dec 2020 18:25:50

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-16T12:25:44', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93f85072-c635-4249-8e5b-feca4faef08e' User entered 'No (N)'	System	16 Dec 2020 18:25:50
	System	16 Dec 2020 18:25:50

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-16T12:25:48', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '93f85072-c635-4249-8e5b-feca4faef08e' User entered '16 Dec 2020 12:25:48'	System	16 Dec 2020 18:25:50
	System	16 Dec 2020 18:25:50

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-19T04:19:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '00878c19-7392-43cc-a175-9da6adb1a5ce'	System	19 Dec 2020 10:19:29
User entered 'No (N)'	System	19 Dec 2020 10:19:29

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-19T04:19:23', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '00878c19-7392-43cc-a175-9da6adb1a5ce'	System	19 Dec 2020 10:19:29
User entered 'No (N)'	System	19 Dec 2020 10:19:29

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-19T04:19:27', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '00878c19-7392-43cc-a175-9da6adb1a5ce' User entered '19 Dec 2020 04:19:27'	System	19 Dec 2020 10:19:29
	System	19 Dec 2020 10:19:29

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:21:24

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:21:24

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:21:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-26T00:30:26', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '52f790e6-f999-4010-b82f-748346a023e4' User entered 'No (N)'	System	26 Dec 2020 06:30:36
	System	26 Dec 2020 06:30:36

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Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-26T00:30:30', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '52f790e6-f999-4010-b82f-748346a023e4' User entered 'No (N)'	System	26 Dec 2020 06:30:36
	System	26 Dec 2020 06:30:36

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2020-12-26T00:30:33', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '52f790e6-f999-4010-b82f-748346a023e4' User entered '26 Dec 2020 00:30:33'	System	26 Dec 2020 06:30:36
	System	26 Dec 2020 06:30:36

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-02T08:04:35', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '68118d61-e4d2-4fb3-b60a-35a90c58aaa1' User entered 'No (N)'	System	02 Jan 2021 14:04:43
	System	02 Jan 2021 14:04:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-02T08:04:39', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '68118d61-e4d2-4fb3-b60a-35a90c58aaa1' User entered 'No (N)'	System	02 Jan 2021 14:04:43
	System	02 Jan 2021 14:04:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-02T08:04:42', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '68118d61-e4d2-4fb3-b60a-35a90c58aaa1' User entered '02 Jan 2021 08:04:42'	System	02 Jan 2021 14:04:43
	System	02 Jan 2021 14:04:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-09T07:55:34', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b1667fd-a02d-4a2d-808f-14b3daa910aa'	System	09 Jan 2021 13:55:45
User entered 'No (N)'	System	09 Jan 2021 13:55:45

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-09T07:55:38', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b1667fd-a02d-4a2d-808f-14b3daa910aa'	System	09 Jan 2021 13:55:45
User entered 'No (N)'	System	09 Jan 2021 13:55:45

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-09T07:55:41', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b1667fd-a02d-4a2d-808f-14b3daa910aa' User entered '09 Jan 2021 07:55:41'	System	09 Jan 2021 13:55:45
	System	09 Jan 2021 13:55:45

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-16T02:50:13', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3951198b-6f59-47c6-9706-d31864aad1c3' User entered 'No (N)'	System	16 Jan 2021 08:50:32
	System	16 Jan 2021 08:50:32

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-16T02:50:20', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3951198b-6f59-47c6-9706-d31864aad1c3'	System	16 Jan 2021 08:50:32
User entered 'No (N)'	System	16 Jan 2021 08:50:32

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-16T02:50:31', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '3951198b-6f59-47c6-9706-d31864aad1c3' User entered '16 Jan 2021 02:50:31'	System	16 Jan 2021 08:50:32
	System	16 Jan 2021 08:50:32

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-23T05:35:40', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b492d81-df88-43ac-b658-b91f5457471e' User entered 'No (N)'	System	23 Jan 2021 11:35:51
	System	23 Jan 2021 11:35:51

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-23T05:35:44', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b492d81-df88-43ac-b658-b91f5457471e' User entered 'No (N)'	System	23 Jan 2021 11:35:51
	System	23 Jan 2021 11:35:51

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-23T05:35:46', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '4b492d81-df88-43ac-b658-b91f5457471e' User entered '23 Jan 2021 05:35:46'	System	23 Jan 2021 11:35:51
	System	23 Jan 2021 11:35:51

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-30T03:24:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '133e9367-7d20-48a9-a627-0378744da661'	System	30 Jan 2021 09:24:08
User entered 'No (N)'	System	30 Jan 2021 09:24:08

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-30T03:24:02', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '133e9367-7d20-48a9-a627-0378744da661'	System	30 Jan 2021 09:24:08
User entered 'No (N)'	System	30 Jan 2021 09:24:08

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-01-30T03:24:05', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '133e9367-7d20-48a9-a627-0378744da661'	System	30 Jan 2021 09:24:08
User entered '30 Jan 2021 03:24:05'	System	30 Jan 2021 09:24:08

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-03-21T08:13:29-05:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b96fe31e-4b92-4150-98e5-4861fc8e88eb'	System	21 Mar 2021 13:13:43
User entered 'No (N)'	System	21 Mar 2021 13:13:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

Have you been exposed to someone with 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 (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-03-21T08:13:32-05:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b96fe31e-4b92-4150-98e5-4861fc8e88eb'	System	21 Mar 2021 13:13:43
User entered 'No (N)'	System	21 Mar 2021 13:13:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-03-21T08:13:40-05:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: 'b96fe31e-4b92-4150-98e5-4861fc8e88eb' User entered '21 Mar 2021 08:13:40'	System	21 Mar 2021 13:13:43
	System	21 Mar 2021 13:13:43

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:21:24

US3922080

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:23:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:21:24
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:21:24

US3922080

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:23:52

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)	30 Apr 2021 22:54:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-03-21T08:13:46-05:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '8ab11508-ecba-4bd8-93fb-c64c7ac2eeab'	System	21 Mar 2021 13:13:55
User entered 'No (N)'	System	21 Mar 2021 13:13:55

US3922080

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:23:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:54:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (70F91AA1-138C-4C77-BCBB-BA7E6F2E8990)', Time: '2021-03-21T08:13:51-05:00', User OID: 'PatientReportedOutcome (US3922080)', ODM File OID: '8ab11508-ecba-4bd8-93fb-c64c7ac2eeab'	System	21 Mar 2021 13:13:55
User entered '21 Mar 2021 08:13:51'	System	21 Mar 2021 13:13:55

US3922080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:57:53
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	25 Nov 2020 15:27:58

US3922080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:57:53
User entered '24 Nov 2020'	Pauline Jackson (b) (4)	25 Nov 2020 15:27:58

US3922080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:57:53
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	25 Nov 2020 15:27:58

US3922080

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:57:53
User entered empty.	Pauline Jackson (b) (4)	25 Nov 2020 15:27:58

US3922080

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:03
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	25 Nov 2020 15:28:01

US3922080

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:50:58
User entered 'I'	System	25 Nov 2020 15:28:01

US3922080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:29
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	28 Dec 2020 14:42:15

US3922080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:29
User entered '28 Dec 2020'	Pauline Jackson (b) (4)	28 Dec 2020 14:42:15

US3922080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:29
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	28 Dec 2020 14:42:15

US3922080

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:29
User entered empty.	Pauline Jackson (b) (4)	28 Dec 2020 14:42:15

US3922080

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:58:38
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	28 Dec 2020 14:42:19

US3922080

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User entered 'I'	System	28 Dec 2020 14:42:19

US3922080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:00
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	27 Jan 2021 16:05:38

US3922080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:00
User entered '27 Jan 2021'	Jennifer Ruiz (b) (4)	27 Jan 2021 16:05:38

US3922080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:00
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	27 Jan 2021 16:05:38

US3922080

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:23:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:00
User entered empty.	Jennifer Ruiz (b) (4)	27 Jan 2021 16:05:38

US3922080

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:09
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	27 Jan 2021 16:05:43

US3922080

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:23:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:00
User entered 'I'	System	27 Jan 2021 16:05:43

US3922080

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:23:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:38:03
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:34:58
User closed query 'Please review AEs in source, UTI noted on 24Feb201 to 01Mar2021, MAAE, treated with con meds, missing severity and relationship assessed by PI and Serious question. Please review and update EDC as necessary, once PI updates necessary required fields.' (Site from CRA). Query 'Please review AEs in source, UTI noted on 24Feb201 to 01Mar2021, MAAE, treated with con meds, missing severity and relationship assessed by PI and Serious question. Please review and update EDC as necessary, once PI updates necessary required fields.' answered with 'Done' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:34:43
DataPoint Un-verified.	Lorine Cook (b) (4) (b) (4)	20 Apr 2021 19:18:23
User opened query 'Please review AEs in source, UTI noted on 24Feb201 to 01Mar2021, MAAE, treated with con meds, missing severity and relationship assessed by PI and Serious question. Please review and update EDC as necessary, once PI updates necessary required fields.' (Site from CRA). User closed query 'Please enter in SAE - for subject reporting on 23Feb2021 about being in the hospital since 04Feb2021 from falling. This is expected to be entered within 24 hours of awareness within the source / EDC / Advarra IRB. ' (Site from CRA). Query 'Please enter in SAE - for subject reporting on 23Feb2021 about being in the hospital since 04Feb2021 from falling. This is expected to be entered within 24 hours of awareness within the source / EDC / Advarra IRB. ' answered with 'updated per query' (Site from CRA). User opened query 'Please enter in SAE - for subject reporting on 23Feb2021 about being in the hospital since 04Feb2021 from falling. This is expected to be entered within 24 hours of awareness within the source / EDC / Advarra IRB. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:54:41
	(b) (4), (b) (6)	20 Apr 2021 15:54:38
	(b) (4), (b) (6)	05 Mar 2021 17:34:46
	lynn yauch (b) (4) (b) (4)	04 Mar 2021 18:20:42
	(b) (4), (b) (6)	03 Mar 2021 22:37:05

US3922080

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:23:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:53:23
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	05 Oct 2020 16:47:23
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	01 Oct 2020 17:29:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 18:07:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 18:07:57
Data point term sent to Coder	System	05 Mar 2021 18:06:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
Data point term sent to Coder	System	05 Mar 2021 18:05:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:25:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:25:40
Data point term sent to Coder	System	21 Oct 2020 12:24:49
Coding entries removed.	lynn yauch (b) (4) (b) (4)	21 Oct 2020 12:24:36
User entered 'WORSENING OF HYPERTENSION' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	21 Oct 2020 12:24:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:22:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:22:16
Data point term sent to Coder	System	05 Oct 2020 16:49:36
User entered 'worsening of hypertensio'	lynn yauch (b) (4)	05 Oct 2020 16:49:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User closed query 'Per CDM: Please clarify Start date of this AE, because the corresponding medication recorded on the Prior and Concomitant Medications form has a Start Date of 09SEP2020 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:44:28
Query 'Per CDM: Please clarify Start date of this AE, because the corresponding medication recorded on the Prior and Concomitant Medications form has a Start Date of 09SEP2020 and update as appropriate.' answered with 'CM indication is "hypertension" and does not directly correspond to AE of "worsening of hypertension" as the medication dosage was changed prior to the start date of the AE.' (Site from DM).	lynn yauch (b) (4)	21 Oct 2020 12:34:49
	(b) (4)	
User opened query 'Per CDM: Please clarify Start date of this AE, because the corresponding medication recorded on the Prior and Concomitant Medications form has a Start Date of 09SEP2020 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:59:28
User entered '02 Oct 2020'	lynn yauch (b) (4)	05 Oct 2020 16:49:24
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	System	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:33:46
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 18:48:54
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 18:48:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 09:26:59
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'confirmed AE is ongoing' (Site from DM).	lynn yauch (b) (4)	05 Feb 2021 13:42:30
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 03:38:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:33:44
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 18:48:54
User entered '24 Feb 2021' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 18:48:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	System	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:49:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

US3922080

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:41:01
User closed query 'Please note that V2 injection was withheld from subject due to the AE ongoing - please review action taken with IP selection and reconcile against source / Investigator to ensure proper answer reflected. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:40:01
Query 'Please note that V2 injection was withheld from subject due to the AE ongoing - please review action taken with IP selection and reconcile against source / Investigator to ensure proper answer reflected. ' answered with 'update source per Sub I review' (Site from CRA).	lynn yauch (b) (4) (b) (4)	20 Nov 2020 18:52:48
DataPoint Un-verified.	lynn yauch (b) (4) (b) (4)	20 Nov 2020 18:52:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	20 Nov 2020 18:52:39
User opened query 'Please note that V2 injection was withheld from subject due to the AE ongoing - please review action taken with IP selection and reconcile against source / Investigator to ensure proper answer reflected. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:26:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Action taken with investigational product is 'None', however, the Visit 2 Day 29 Exposure Form states, "Physician withheld dose due to Adverse Event". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:48:12
Query 'Per CDM: Action taken with investigational product is 'None', however, the Visit 2 Day 29 Exposure Form states, "Physician withheld dose due to Adverse Event". Please clarify and update as appropriate.' answered with 'updated to NA' (Site from DM).	lynn yauch (b) (4) (b) (4)	28 Oct 2020 15:51:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	28 Oct 2020 15:47:46
User opened query 'Per CDM: Action taken with investigational product is 'None', however, the Visit 2 Day 29 Exposure Form states, "Physician withheld dose due to Adverse Event". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:57:03
User entered 'None (NONE)'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User closed query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:38:33
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:09:35
Query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' answered with 'updated' (Site from DM).	lynn yauch (b) (4) (b) (4)	12 Nov 2020 15:56:21
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	12 Nov 2020 15:54:31
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:56:17
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User opened query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:17:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Oct 2020 12:39:34
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	21 Oct 2020 12:39:34
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	21 Oct 2020 12:39:07
User entered '0'	System	21 Oct 2020 12:39:07
	lynn yauch (b) (4)	05 Oct 2020 16:49:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:09:37
User closed query 'please note that concomitant medications indicate that patient started losartan 25mg and amlodipine 10mg on 21Oct2020 for treatment of HTN. Please review AE in source and edc and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:09:32
Query 'please note that concomitant medications indicate that patient started losartan 25mg and amlodipine 10mg on 21Oct2020 for treatment of HTN. Please review AE in source and edc and update as necessary.' answered with 'updated' (Site from CRA).	lynn yauch (b) (4)	12 Nov 2020 15:56:31
User entered '1' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 15:54:31
User opened query 'please note that concomitant medications indicate that patient started losartan 25mg and amlodipine 10mg on 21Oct2020 for treatment of HTN. Please review AE in source and edc and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:56:14
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	21 Oct 2020 12:39:07
User entered '1'	lynn yauch (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered '0'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:33:40
User closed query 'Source notes that AE was recovered/resolved on 24Feb2021, please review source and medical records against EDC to determine if accurate or if status was still ongoing by the time of LTFU status (25Feb2021). If still was ongoing, please consider updating source and EDC per eCCGs V5.0, to outcome of 'Unknown' and leaving date of resolution blank. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:33:35
Query 'Source notes that AE was recovered/resolved on 24Feb2021, please review source and medical records against EDC to determine if accurate or if status was still ongoing by the time of LTFU status (25Feb2021). If still was ongoing, please consider updating source and EDC per eCCGs V5.0, to outcome of 'Unknown' and leaving date of resolution blank. Thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 18:49:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 18:49:12
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 18:48:54
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 16:04:42
User opened query 'Source notes that AE was recovered/resolved on 24Feb2021, please review source and medical records against EDC to determine if accurate or if status was still ongoing by the time of LTFU status (25Feb2021). If still was ongoing, please consider updating source and EDC per eCCGs V5.0, to outcome of 'Unknown' and leaving date of resolution blank. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:04:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	lynn yauch (b) (4)	05 Oct 2020 16:49:24

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

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 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	20 Apr 2021 18:49:12
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	20 Apr 2021 18:48:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:52:57
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:23:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	System	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	System	05 Oct 2020 16:49:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:07
User entered	System	05 Mar 2021 15:10:02
'USA-US212-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	05 Mar 2021 15:10:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:19:11
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Septic shock, LLT: Septic shock - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 19:51:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 19:51:57
Data point term sent to Coder	System	05 Mar 2021 19:51:13
User entered 'SEPTIC SHOCK' reason for change:	lynn yauch (b) (4)	05 Mar 2021 19:50:17
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 19:50:12
User entered 'SEPSIC SHOCK' reason for change:	lynn yauch (b) (4)	05 Mar 2021 19:49:56
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 18:06:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
Data point term sent to Coder	System	05 Mar 2021 18:05:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
Data point term sent to Coder	System	04 Mar 2021 18:16:19
User entered 'Sepsis shock'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:19:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'No (N)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:19:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'No (N)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	28 Apr 2021 12:05:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 16:38:51
User closed query 'PV Query: It was reported that the subject was admitted to ICU on 03 Feb 2021 due to septic shock. Please consider updating the event start date for septic shock to 03 Feb 2021. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:27:04
Query 'PV Query: It was reported that the subject was admitted to ICU on 03 Feb 2021 due to septic shock. Please consider updating the event start date for septic shock to 03 Feb 2021. If not updating, please clarify.' answered with 'updated' (Site from Safety).	Lorine Cook (b) (4)	23 Apr 2021 14:45:54
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	23 Apr 2021 14:45:37
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: It was reported that the subject was admitted to ICU on 03 Feb 2021 due to septic shock. Please consider updating the event start date for septic shock to 03 Feb 2021. If not updating, please clarify.' (Site from Safety).	Lorine Cook (b) (4)	23 Apr 2021 14:45:37
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 13:03:23
DataPoint Verified.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
	(b) (4), (b) (6)	12 Apr 2021 15:52:23
User closed query 'Source indicates onset date as 04Feb2021, however, hospitalized on 03Feb2021. Please review EDC and source / records and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:52:21
Query 'Source indicates onset date as 04Feb2021, however, hospitalized on 03Feb2021. Please review EDC and source / records and update where necessary.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	08 Apr 2021 22:48:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Feb 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Apr 2021 22:48:16
User opened query 'Source indicates onset date as 04Feb2021, however, hospitalized on 03Feb2021. Please review EDC and source / records and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:16:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '03 Feb 2021'	lynn yauch (b) (4)	04 Mar 2021 18:15:28

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Folder: Adverse Events

Form: Adverse Events (2)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:16:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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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 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	System	04 Mar 2021 18:15:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:10
DataPoint Un-verified.	lynn yauch (b) (4)	14 Apr 2021 19:39:52
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 19:39:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:16:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:12
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:29:08
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).	lynn yauch (b) (4)	16 Apr 2021 18:00:07
	(b) (4)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 17:59:56
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Apr 2021 17:59:56
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 17:59:56
DataPoint Un-verified.	lynn yauch (b) (4)	16 Apr 2021 17:59:56
	(b) (4)	
User entered '07 Feb 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 17:59:56
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Apr 2021 19:41:31
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	14 Apr 2021 19:39:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 11:58:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	System	04 Mar 2021 18:15:28

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
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	04 Mar 2021 18:19:16
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	04 Mar 2021 18:15:28
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'additional information will be updated once available Close.'. However, request you please keep this query open until site get required information and data recorded as appropriate. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Apr 2021 11:02:37
DataPoint Verified.	Michele Reynolds (b) (4) (b) (4), (b) (6)	21 Apr 2021 21:56:47 21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
Query 'PER CDM: Re-Query: As per previous response it was reported as 'additional information will be updated once available Close.'. However, request you please keep this query open until site get required information and data recorded as appropriate. Thank you.' answered with 'Final Medical records sent 21/APR/2021' (Site from DM). User closed query 'Requires inpatient or prolongation System 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).	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 13:55:12 14 Apr 2021 19:39:52
Query 'Requires inpatient or prolongation of existing System 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).		14 Apr 2021 19:39:52
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). DataPoint Verified.	System (b) (4), (b) (6)	14 Apr 2021 19:28:35 07 Apr 2021 20:15:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'additional information will be updated once available Close.'. However, request you please keep this query open until site get required information and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:39:34
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 10:39:30
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 'additional information will be updated once available' (Site from System).	lynn yauch (b) (4)	04 Mar 2021 18:20:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	04 Mar 2021 18:19:16
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	04 Mar 2021 18:19:16
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	04 Mar 2021 18:19:16
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	04 Mar 2021 18:19:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	04 Mar 2021 18:15:28
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:15:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '03 Feb 2021'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:35:39
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:33:53
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'updated per query' (Site from Safety).	lynn yauch (b) (4)	14 Apr 2021 19:40:25
DataPoint Un-verified.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 19:39:52
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 19:39:52
Query 'Per recent medical records received, 23Mar2021 discharge date noted. Please review and update SAEs, as applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:52:36
User opened query 'Per recent medical records received, 23Mar2021 discharge date noted. Please review and update SAEs, as applicable.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:18:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:52
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 12:00:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:35:43
User closed query 'Please review and clarify if patient was admitted to ICU or not. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:27:38
Query 'Please review and clarify if patient was admitted to ICU or not. Thank you.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	14 Apr 2021 19:40:41
DataPoint Un-verified.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 19:28:35
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 19:28:35
User opened query 'Please review and clarify if patient was admitted to ICU or not. Thank you.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:18:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:00:07
User closed query 'Please clarify if 4 or 5 days, (03-07Feb2021), depending on time of admission/discharge from ICU.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 20:59:49
Query 'Please clarify if 4 or 5 days, (03-07Feb2021), depending on time of admission/discharge from ICU.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 18:54:45
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 18:53:59
User entered '4' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 18:53:59
User opened query 'Please clarify if 4 or 5 days, (03-07Feb2021), depending on time of admission/discharge from ICU.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:02:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:59:43
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	14 Apr 2021 19:34:53
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	14 Apr 2021 19:34:53
DataPoint Un-verified.	lynn yauch (b) (4)	14 Apr 2021 19:34:53
User entered '5' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 19:34:53
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	14 Apr 2021 19:28:35
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	lynn yauch (b) (4) (b) (4)	04 Mar 2021 18:15:28

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:14:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 13:29:14
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. 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) (6)	19 Apr 2021 07:07:26
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 'Con Meds will be updated once documented appropriately' (Site from Safety).	lynn yauch (b) (4)	16 Apr 2021 17:55:39
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Con Meds will be updated once documented appropriately' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 17:54:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:18:06

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 22:51:12
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 11:59:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'I'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered '0'	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:35:52
User closed query 'PV Query: Medical records indicate Septic Shock has resolved. Source document reports septic shock as not resolved. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:34:18
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 18:34:11
Query 'PV Query: Medical records indicate Septic Shock has resolved. Source document reports septic shock as not resolved. Please reconcile.' answered with 'updated' (Site from Safety).	lynn yauch (b) (4)	14 Apr 2021 19:42:42
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	lynn yauch (b) (4)	14 Apr 2021 19:42:26
DataPoint Un-verified.	lynn yauch (b) (4)	14 Apr 2021 19:41:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 19:41:31
Query 'Please review against source and update as necessary - currently does not indicate an outcome, thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:53:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:52:59
User opened query 'Please review against source and update as necessary - currently does not indicate an outcome, thank you.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:17:39
User opened query 'PV Query: Medical records indicate Septic Shock has resolved. Source document reports septic shock as not resolved. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:39:56

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 11:58:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	lynn yauch (b) (4)	04 Mar 2021 18:15:28

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:17:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered empty.	lynn yauch (b) (4)	04 Mar 2021 18:15:28
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:01:42
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.	(b) (4), (b) (6)	22 Apr 2021 13:01:34
' (Site from Safety).		
User closed query 'Per DM CLR: Narrative = FALL. 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)	22 Apr 2021 11:04:10
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:31:21
User closed query 'Source indicates a progress note from Investigator on 12Mar2021, please review and update EDC if possible.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:31:07
Query 'Per DM CLR: Narrative = FALL. 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 'the fall was due to her being ill with the septic shock and does not need to be reported as a separate AE PI confirmed ' (Site from DM).	Lorine Cook (b) (4)	21 Apr 2021 14:22:13

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with '03/FEB/21 Coronavirus(covid-19)/Influenza PCR: NEGATIVE' (Site from Safety).	Lorine Cook (b) (4)	21 Apr 2021 13:52:24
Query 'Source indicates a progress note from Investigator on 12Mar2021, please review and update EDC if possible.' answered with 'Updated with note' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 13:43:28
User entered 'Update 12/MAR/21 PT admitted to hospital 03/FEB/21 after presenting to ER c arm pain, hypotension, Arterial Fib with rapid ventricular response. Found to have septic shock and admitted to ICU. Treated with IV antibiotics. CRP above 21, ESR grader then 130, blood returned strep-dysgalactiae seem to recover but had persistent fever but complained of pain and weakness of extremities. Still in hospital as of 12/MAR/21 work up in progress. We have hospital records from admid-24/FEB/21sent for rest of her records. SUBJECT CONTACTED SITE ON 23/FEB/2021 STATED THAT SHE FELL IN BATHROOM AND NOW IS CURRENTLY STILL IN HOSPITAL UNABLE TO WALK SUBJECT STATES SHE DID NOT LOSE CONSCIOUSNESS . THEY ARE RUNNING TEST. SITE REQUESTED MEDICAL RECORD.' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 13:43:01
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Last of the Medical Record sent. ' (Site from Safety).	Lorine Cook (b) (4)	21 Apr 2021 12:58:32
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:37

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Source indicates a progress note from Investigator on 12Mar2021, please review and update EDC if possible.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:01:35
	(b) (4), (b) (6)	07 Apr 2021 20:17:52
Query 'PV Query: Medical records indicate Septic Shock has resolved. Source document reports septic shock as not resolved. Please reconcile.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:39:27
User opened query 'PV Query: Medical records indicate Septic Shock has resolved. Source document reports septic shock as not resolved. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:39:16
User opened query 'Per DM CLR: Narrative = FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 22:51:03
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 12:00:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.	(b) (4), (b) (6)	11 Mar 2021 11:57:46
' (Site from Safety).		
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Mar 2021 18:18:45
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Mar 2021 18:18:45

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE ON 23/FEB/20201 STATED THAT SHE FELL IN BATHROOM AND NOW IS CURRENTLY STILL IN HOSPITAL UNABLE TO WALK SUBJECT STATES SHE DID NOT LOSE Consciousness . THEY ARE RUNNING TEST. SITE REQUESTED MEDICAL RECORD.' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	04 Mar 2021 18:18:45
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Mar 2021 18:15:28
User entered empty.	lynn yauch (b) (4) (b) (4)	04 Mar 2021 18:15:28

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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 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'I'	System	04 Mar 2021 18:15:28

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Folder: Adverse Events

Form: Adverse Events (2)

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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 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14
User entered 'I'	System	04 Mar 2021 18:15:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 19:28:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Mar 2021 18:06:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Mar 2021 18:05:14

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:09
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:08:21
Query 'Per MM: Please update when information or additional medical records available.' answered with 'all available information has been updated' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 17:57:24
	(b) (4)	
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:42:51
User closed query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:42:51
Query 'Per MM: please provide the outcome of the event' answered with 'pending PI review of additional medical records' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:54:57
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Thrombophlebitis superficial, LLT: Superficial venous thrombosis of arm - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 10:09:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 10:09:03
	(b) (4)	
User opened query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:51:45
Data point term sent to Coder	System	12 Mar 2021 17:20:35
User entered 'Superficial Venous Thrombosis Cepherin vein Right UE'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:12
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:14
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:15
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:18
User entered '08 Feb 2021'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:20:20
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:20:33

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Form: Adverse Events (4)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:40:25
User closed query 'Source notes end date of 23Mar2021, which is after LTFU date. Please review and update as necessary. Due to not SAE, possibly needing to stay Yes for ongoing, and updating Outcome as 'Unknown' (see eCCGs V5.0 for guidance). Please review source and EDC and update where necessary.' (Site from CRA). Query 'Source notes end date of 23Mar2021, which is after LTFU date. Please review and update as necessary. Due to not SAE, possibly needing to stay Yes for ongoing, and updating Outcome as 'Unknown' (see eCCGs V5.0 for guidance). Please review source and EDC and update where necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:40:18
	Lorine Cook (b) (4)	20 Apr 2021 19:42:07
	(b) (4)	
User opened query 'Source notes end date of 23Mar2021, which is after LTFU date. Please review and update as necessary. Due to not SAE, possibly needing to stay Yes for ongoing, and updating Outcome as 'Unknown' (see eCCGs V5.0 for guidance). Please review source and EDC and update where necessary.'	(b) (4), (b) (6)	20 Apr 2021 16:21:48
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:23:01
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:23:03
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:20:33

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Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:23:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:23:11
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:29
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:27
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:26
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:24
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:23
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:22
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:44
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:43
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:41
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:40
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:37
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:35
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:38
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:58
User closed query 'Source indicates Con Meds 12, 13 taken for this AE. Please review and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:39:57
Query 'Source indicates Con Meds 12, 13 taken for this AE. Please review and update where necessary.' answered with 'Done' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:26:34
User entered '0' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:23:38
User opened query 'Source indicates Con Meds 12, 13 taken for this AE. Please review and update where necessary.' (Site from CRA).		
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 15:30:06
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:30:06
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:20:33
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:40:01
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 19:25:31
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:25:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:24:00
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:59:19
User closed query 'Con procedure #16 listed, however, box is blank in source. Please review source and EDC and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:59:13
Query 'Con procedure #16 listed, however, box is blank in source. Please review source and EDC and reconcile as needed.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:26:40
User entered '1' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:29:36
User opened query 'Con procedure #16 listed, however, box is blank in source. Please review source and EDC and reconcile as needed.' (Site from CRA).		
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 16:29:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:24:02
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:35:56
User closed query 'source indicates date of resolution as 23Mar2021 (hospital discharge date), however, subject was LTFU as of 25Feb2021. Please review source and EDC and consider updating if needed, per eCCG V5.0, with outcome as 'Unknown' and keeping end date blank since ongoing at time of LTFU and if not relevant to SAEs. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:59:18
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:39:46
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:41:55
Query 'source indicates date of resolution as 23Mar2021 (hospital discharge date), however, subject was LTFU as of 25Feb2021. Please review source and EDC and consider updating if needed, per eCCG V5.0, with outcome as 'Unknown' and keeping end date blank since ongoing at time of LTFU and if not relevant to SAEs. Thank you.' answered with 'Updated ' (Site from CRA).	(b) (4)	
	Lorine Cook (b) (4)	20 Apr 2021 19:26:47
	(b) (4)	
User opened query 'source indicates date of resolution as 23Mar2021 (hospital discharge date), however, subject was LTFU as of 25Feb2021. Please review source and EDC and consider updating if needed, per eCCG V5.0, with outcome as 'Unknown' and keeping end date blank since ongoing at time of LTFU and if not relevant to SAEs. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:25:22
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:27:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:27:31

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Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:27:31
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:20:33
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:26
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:00
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:27
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:20:33
	(b) (4)	

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 17:20:33

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:20:33

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:25:44

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:30:59
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:08:47
Query 'Per MM: Please update when information or additional medical records available.' answered with 'all available information has been updated' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 17:57:53
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:43:30
User closed query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:43:30
Query 'Per MM: please provide the outcome of the event' answered with 'pending PI review of additional medical records' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:55:34
User opened query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:51:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Cystitis - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 17:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 17:23:47
Data point term sent to Coder	System	12 Mar 2021 17:22:36
User entered 'Cystitis'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:26
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:23
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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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 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:21
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:03
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:22:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 17:22:58
User entered '03 Feb 2021' reason for change: Data Entry Error	Lorine Cook (b) (4)	12 Mar 2021 17:22:58
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:21:43
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:18
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User entered empty.	System	12 Mar 2021 17:21:43

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:57:08
User closed query 'Source indicates recovered/resolved as of 01Mar2021, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:56:22
Query 'Source indicates recovered/resolved as of 01Mar2021, please review and reconcile.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:44:14
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
User opened query 'Source indicates recovered/resolved as of 01Mar2021, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:31:27
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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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 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:56:33
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
User entered '01 Mar 2021' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:15
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:13
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User entered empty.	System	12 Mar 2021 17:21:43

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:23:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 17:23:11
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4)	12 Mar 2021 17:23:11
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:21:43
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:10
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:06
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:05
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:04
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

US3922080

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:02
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:34:01
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:59
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:57
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:56
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:55
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:40
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:39
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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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 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:37
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:57:17
User closed query 'Per Investigator progress notes, con med taken for treatment. Please review AE source page, which currently is blank and EDC to determine if update to Con Med check box is needed. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:57:15
Query 'Per Investigator progress notes, con med taken for treatment. Please review AE source page, which currently is blank and EDC to determine if update to Con Med check box is needed. Thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:44:35
User entered '0' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 19:44:01
User opened query 'Per Investigator progress notes, con med taken for treatment. Please review AE source page, which currently is blank and EDC to determine if update to Con Med check box is needed. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:32:41
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 17:41:13
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:41:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:21:43
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:57:19
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:48
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:43
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:57:24
User closed query 'source notes recovered/resolved on 01Mar2021, please reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:57:23
Query 'source notes recovered/resolved on 01Mar2021, please reconcile as needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:44:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:44:01
User opened query 'source notes recovered/resolved on 01Mar2021, please reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:30:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:30:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:30:34
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:21:43
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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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 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:51
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:52
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:21:43

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User entered '0'	System	12 Mar 2021 17:23:11

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:25:44
User entered '1'	System	12 Mar 2021 17:21:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:25:44

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:15
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:09:10
Query 'Per MM: Please update when information or additional medical records available.' answered with 'all available information has been updated' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 17:58:21
	(b) (4)	
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:44:00
User closed query 'Per MM: please provide the outcome of the event.'	(b) (4), (b) (6)	13 Apr 2021 08:44:00
' (Site from DM).		
Query 'Per MM: please provide the outcome of the event.'	lynn yauch (b) (4)	08 Apr 2021 22:56:12
' answered with 'pending PI review of additional medical records' (Site from DM).	(b) (4)	
User opened query 'Per MM: please provide the outcome of the event.'	(b) (4), (b) (6)	29 Mar 2021 09:52:11
' (Site from DM).		
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Normocytic anaemia, LLT: Normocytic anemia - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 08:21:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 08:21:00
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 17:53:19
Coding entries removed.	lynn yauch (b) (4)	24 Mar 2021 17:52:45
	(b) (4)	
User entered 'CHRONIC NORMOCYTIC anemia' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:52:45
	(b) (4)	

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Normocytic anaemia, LLT: Normocytic anaemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 07:07:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 07:07:55
Data point term sent to Coder	System	12 Mar 2021 17:25:41
User entered 'Chronic normocytic'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:20
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:21
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:23
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:54:29
User closed query 'Please review source and clarify / correct if needed (per ALCOA +CCEA principles), if 03Feb2021 or 08Feb2021 onset date, currently hard to decipher. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:54:28
Query 'Please review source and clarify / correct if needed (per ALCOA +CCEA principles), if 03Feb2021 or 08Feb2021 onset date, currently hard to decipher. Thank you.' answered with '03/FEB/2021 fixed in source. ' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:50:14
	(b) (4)	
User opened query 'Please review source and clarify / correct if needed (per ALCOA +CCEA principles), if 03Feb2021 or 08Feb2021 onset date, currently hard to decipher. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:36:35
User entered '03 Feb 2021'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:37:57
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:25:35

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:00
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:02
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:04
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:25:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:09
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:10
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:11
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:13
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:14
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:16
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:18
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:20
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:24
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(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.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:28
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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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.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:30
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:31
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:34
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:38:36
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:54:49
User closed query 'Source currently blank under other action taken section. Please review source and progress notes / medical records to confirm / determine if necessary to update answer or just need to document within source as 'None' and inadvertently missed the answer. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:54:46
Query 'Source currently blank under other action taken section. Please review source and progress notes / medical records to confirm / determine if necessary to update answer or just need to document within source as 'None' and inadvertently missed the answer. Thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	20 Apr 2021 19:53:29
User entered '0' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:39:53
User opened query 'Source currently blank under other action taken section. Please review source and progress notes / medical records to confirm / determine if necessary to update answer or just need to document within source as 'None' and inadvertently missed the answer. Thank you.' (Site from CRA).		
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 17:41:46
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:41:46
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:25:35
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:54:42
DataPoint Un-verified.	Lorine Cook (b) (4)	20 Apr 2021 19:53:19
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:53:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:40:47
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:40:50
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:54:54
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:53:19
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	15 Mar 2021 15:30:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	15 Mar 2021 15:30:48
User opened query 'Data is required. Please complete.' (Site from System).	lynn yauch (b) (4)	15 Mar 2021 15:30:48
User entered empty.	(b) (4)	
	System	12 Mar 2021 17:25:35
	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:40:52
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:08
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:40:53
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:25:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 17:25:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:23:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:25:35

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:39
User closed query 'Please note that source states Chronic LVH, appears to be an abbreviation. Please include full medical diagnosis, as this is not a common, known diagnosis. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:37
Query 'Please note that source states Chronic LVH, appears to be an abbreviation. Please include full medical diagnosis, as this is not a common, known diagnosis. Thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:07:30
	(b) (4)	
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 06:54:22
Query 'Per MM: Please update when information or additional medical records available.' answered with '69% LVEF shown on ECHO per PI/Medical records' (Site from DM).	Lorine Cook (b) (4)	20 Apr 2021 19:57:55
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:00
User opened query 'Please note that source states Chronic LVH, appears to be an abbreviation. Please include full medical diagnosis, as this is not a common, known diagnosis. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:47:22
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:46:28
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:44:49
User closed query 'Per MM: please provide the outcome of the event.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:44:49
Query 'Per MM: please provide the outcome of the event. ' answered with 'pending PI review of additional medical records' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:56:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM: please provide the outcome of the event. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:52:27
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: Left ventricular hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 00:27:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 00:27:48
Data point term sent to Coder	System	15 Mar 2021 15:36:39
Coding entries removed.	lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:35:40
User entered 'CHRONIC Left ventricular hypertrophy' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:35:40
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: LVH - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:14:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:14:16
Data point term sent to Coder	System	12 Mar 2021 17:27:47
User entered 'Chronic LVH'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:27:13

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:04
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:15
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:17
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:19
User entered '03 Feb 2021'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:21
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:27:13

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:23
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:25
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:26
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:27:13

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:48:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:10
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:14
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:16
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:18
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:20
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:25
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:28
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:29
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:31
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:33
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:35
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:44
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:46
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:50
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:54:00
User closed query 'Source AE page currently blank under other action taken section, please review and update source and/or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:53
Query 'Source AE page currently blank under other action taken section, please review and update source and/or EDC as needed.' answered with 'correct' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:11:56
User opened query 'Source AE page currently blank under other action taken section, please review and update source and/or EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:58:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 17:55:08
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:55:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	12 Mar 2021 17:27:13
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:55
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:57
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:51
User closed query 'Per eCCGs V5.0, if subject is LTFU, ongoing event, to be updated to outcome of 'Unknown' with end date blank. Per review source and EDC and update as needed.' (Site from CRA). Query 'Per eCCGs V5.0, if subject is LTFU, ongoing event, to be updated to outcome of 'Unknown' with end date blank. Per review source and EDC and update as needed.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:53:48
	Lorine Cook (b) (4)	21 Apr 2021 14:12:13
	(b) (4)	
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:11:30
	(b) (4)	
User opened query 'Per eCCGs V5.0, if subject is LTFU, ongoing event, to be updated to outcome of 'Unknown' with end date blank. Per review source and EDC and update as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:59:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:31:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:31:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:31:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:27:13
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:57:00
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:57:02
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:27:13
	(b) (4)	

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 17:27:13

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:27:13

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:40:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:42
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:09:28
Query 'Per MM: Please update when information or additional medical records available.' answered with 'all available information has been updated' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 18:02:21
	(b) (4)	
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:45:23
User closed query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:45:23
Query 'Per MM: please provide the outcome of the event' answered with 'pending PI review of additional medical records' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:57:28
	(b) (4)	
User opened query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:52:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Degenerative joint disease - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 08:23:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 08:23:52
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 17:59:27
Coding entries removed.	lynn yauch (b) (4)	24 Mar 2021 17:58:44
	(b) (4)	
User entered 'DEGENERATIVE JOINT DISEASE RIGHT knee AND RIGHT ANKLE' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:58:44
	(b) (4)	

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 07:44:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 07:44:17
Data point term sent to Coder	System	12 Mar 2021 17:29:49
User entered 'Degenerative Joint Disease Right and Right ankle'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:39
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:09
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:01
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:17
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:20
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:24
User entered '03 Feb 2021'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:26
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:28:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:29
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 05:45:41
Query 'Per MM, please provide the end date.' answered with 'AE is ongoing, subject is LTFU' (Site from DM).	lynn yauch (b) (4)	26 Apr 2021 19:13:39
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:44:29
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:31
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:34
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:28:56

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:41:09
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:39
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:43
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:46
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:49
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:20:53
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:02
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:05
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Form: Adverse Events (8)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:09
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:11
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:25
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:29
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:32
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:41
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:35
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(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.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:44
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:53
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 17:47:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:28:56
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:21:56
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michele Reynolds (b) (4)	22 Apr 2021 11:09:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'Please answer query from DM CLR below.' (Site from CRA). Query 'Please answer query from DM CLR below.' answered with 'updated ' (Site from CRA). Query ' Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' answered with 'Subject had X-ray's ' (Site from DM).	(b) (4), (b) (6) Lorine Cook (b) (4) Lorine Cook (b) (4)	21 Apr 2021 14:52:51 21 Apr 2021 14:20:34 21 Apr 2021 14:19:52
User opened query 'Please answer query from DM CLR below.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 17:23:21 20 Apr 2021 17:21:58
User opened query ' Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:26:02
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 17:47:02
User entered '0'	(b) (4) Lorine Cook (b) (4)	12 Mar 2021 17:28:56

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:59
User closed query 'Per eCCGs V5.0, any not recovered / not resolved AEs are to be updated to outcome of 'unknown' if ongoing at time of LTFU (25Feb2021). Please review source and EDC and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:52:57
Query 'Per eCCGs V5.0, any not recovered / not resolved AEs are to be updated to outcome of 'unknown' if ongoing at time of LTFU (25Feb2021). Please review source and EDC and update as necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:20:50
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 14:20:14
User opened query 'Per eCCGs V5.0, any not recovered / not resolved AEs are to be updated to outcome of 'unknown' if ongoing at time of LTFU (25Feb2021). Please review source and EDC and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:31:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:31:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Mar 2021 15:31:15
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:28:56
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:44
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:46
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:28:56
	(b) (4)	

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 17:28:56

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Form: Adverse Events (8)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:28:56

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:26:45

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:25:39
User closed query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:09:48
Query 'Per MM: Please update when information or additional medical records available.' answered with 'all available information has been updated' (Site from DM).	lynn yauch (b) (4)	16 Apr 2021 17:58:56
User opened query 'Per MM: Please update when information or additional medical records available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:45:52
User closed query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:45:52
Query 'Per MM: please provide the outcome of the event' answered with 'pending PI review of additional medical records' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:57:55
User opened query 'Per MM: please provide the outcome of the event' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:52:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 17:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 17:31:47
Data point term sent to Coder	System	12 Mar 2021 17:30:58
User entered 'Hyponatremia'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:26:22
User entered 'Yes (Y)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:26:24
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:26:26
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'Please clarify current date in source / EDC 02Feb2021, as patient was hospitalized on 03Feb2021, and most events note start date of 03Feb2021. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:51:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:51:27
Query 'Please clarify current date in source / EDC 02Feb2021, as patient was hospitalized on 03Feb2021, and most events note start date of 03Feb2021. Thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:34:44
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 14:33:41
User entered '03 Feb 2021' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:33:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:27:20
User opened query 'Please clarify current date in source / EDC 02Feb2021, as patient was hospitalized on 03Feb2021, and most events note start date of 03Feb2021. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:27:02
User entered '02 Feb 2021'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:27:16
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User entered empty.	System	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:37:10
User closed query 'Source notes end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:37:03
Query 'Source notes end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' answered with 'per PI end dated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:35:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 14:33:41
User opened query 'Source notes end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:29:05

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:37:13
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 14:33:41
User entered '24 Feb 2021' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:33:41
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:17
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:20
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User entered empty.	System	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:28
User entered 'No (N)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:32
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:34
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

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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 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:42
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:44
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:48
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:53
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:55
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:57
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:29:59
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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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 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:01
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:04
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:06
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:08
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:08
User closed query 'Please clarify correct response against source, which currently is blank in other action taken, field. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:52:05
Query 'Please clarify correct response against source, which currently is blank in other action taken, field. Thank you.' answered with 'correct' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:36:30
User opened query 'Please clarify correct response against source, which currently is blank in other action taken, field. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:30:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 18:00:35
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	24 Mar 2021 18:00:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:30:37
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:36
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

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Folder: Adverse Events

Form: Adverse Events (9)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:39
User entered '0'	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:01
User closed query 'Source notes recovered with an end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:52:00
Query 'Source notes recovered with an end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' answered with 'Per PI end date 24/FEB/2021' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:37:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	21 Apr 2021 14:33:41
Data Entry Error		

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Source notes recovered with an end date of 24Feb2021. Please review source and EDC and determine if end date is accurate as is, or if it is due to subject LTFU (25Feb2021). If due to status of LTFU, please ensure EDC and source are updated to reflect outcome of 'Unknown' with ongoing 'yes' and date left blank. Please review current information and eCCGs V5.0 as needed, in order to clarify if needing updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:30:56
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 15:32:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 15:32:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Mar 2021 15:32:24
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:30:37
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[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 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:30:59
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:01
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User entered '0'	System	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:45
User entered 'I'	System	12 Mar 2021 17:30:37

US3922080

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:26:45

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:22
User coded data point as SOC: Gastrointestinal disorders, HLGt: Tongue conditions, HLT: Tongue disorders, PT: Tongue ulceration, LLT: Tongue ulceration - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 09:50:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 09:50:20
Data point term sent to Coder	System	24 Mar 2021 18:02:37
User entered 'left dorsal tongue ulcerative lesion'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:42
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:20
User entered 'Yes (Y)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:31
User entered 'No (N)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:29
User entered 'No (N)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:25
User entered '09 Jan 2021'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:12
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:02:03

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:27
User entered 'Yes (Y)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:09
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:11
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 18:02:03

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:36
User entered 'No (N)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:52:29
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:52:44
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:42
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:39
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:38
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:35
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:32
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:30
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:27
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:22
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:40
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:41
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:43
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:54:45
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

US3922080

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:49:50
User closed query 'Source notes con med #63 given for treatment of this AE, please review source and EDC and reconcile as needed. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:49:48
Query 'Source notes con med #63 given for treatment of this AE, please review source and EDC and reconcile as needed. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:28:22
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:27:20
	(b) (4)	
User opened query 'Source notes con med #63 given for treatment of this AE, please review source and EDC and reconcile as needed. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 17:34:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:34:51
User entered '0'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'Con procedure currently listed as #24 (biopsy), which is diagnostic. Source and EDC note Con Procedure for action taken, however, this would mean after diagnosing ulcerative lesion, an additional procedure was performed for treatment. Please review source and EDC and consider updating selection and unchecking con procedures box for this AE. thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:49:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:49:53
Query 'Con procedure currently listed as #24 (biopsy), which is diagnostic. Source and EDC note Con Procedure for action taken, however, this would mean after diagnosing ulcerative lesion, an additional procedure was performed for treatment. Please review source and EDC and consider updating selection and unchecking con procedures box for this AE. thank you.' answered with 'confirmed no con procedure ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:28:04
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:27:20
User opened query 'Con procedure currently listed as #24 (biopsy), which is diagnostic. Source and EDC note Con Procedure for action taken, however, this would mean after diagnosing ulcerative lesion, an additional procedure was performed for treatment. Please review source and EDC and consider updating selection and unchecking con procedures box for this AE. thank you.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:55:35

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Con procedure currently listed as #24 (biopsy), which is diagnostic. Source and EDC note Con Procedure for action taken, however, this would mean after diagnosing ulcerative lesion, an additional procedure was performed for treatment. Please review source and EDC and consider updating to 'None' if no treatment was provided to subject (con meds and or con procedures, etc.) for this AE. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:54:58
User opened query 'Con procedure currently listed as #24 (biopsy), which is diagnostic. Source and EDC note Con Procedure for action taken, however, this would mean after diagnosing ulcerative lesion, an additional procedure was performed for treatment. Please review source and EDC and consider updating to 'None' if no treatment was provided to subject (con meds and or con procedures, etc.) for this AE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:34:48
User closed query 'Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 09:57:34
Query 'Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' answered with 'updated Con procedure to diagnostic per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 23:01:02
User opened query 'Per DM CLR: Other Action Taken=Concomitant Procedure. However, the procedure recorded is not therapeutic in nature but diagnostic. Review response and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:26:55
User entered 'I'	lynn yauch (b) (4) (b) (4)	24 Mar 2021 18:02:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
User closed query 'Due to subject LTFU (25Feb2021), please note per CCGs V5.0, all AEs not recovered / ongoing after this, are to be updated under outcome as 'unknown' with end date blank. Please review source and EDC and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:50:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:10
Query 'Due to subject LTFU (25Feb2021), please note per CCGs V5.0, all AEs not recovered / ongoing after this, are to be updated under outcome as 'unknown' with end date blank. Please review source and EDC and update as needed.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:28:40
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 14:27:20
User opened query 'Due to subject LTFU (25Feb2021), please note per CCGs V5.0, all AEs not recovered / ongoing after this, are to be updated under outcome as 'unknown' with end date blank. Please review source and EDC and update as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:53:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:53:55
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:53:53
User entered empty.	lynn yauch (b) (4)	24 Mar 2021 18:02:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 18:02:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:23:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 18:02:03

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:42
User entered	(b) (4), (b) (6)	15 Apr 2021 18:38:06
'USA-US212-2021-mRNA-1273-P301000006'		

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:40
User coded data point as SOC: Vascular disorders, HLT: Vascular infections and inflammations, HLT: Vasculitides NEC, PT: Polyarteritis nodosa, LLT: Polyarteritis nodosa - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:27:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 19:27:53
Data point term sent to Coder	System	14 Apr 2021 19:27:31
User entered 'polyarteritis nodosa'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:36
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:34
User entered 'No (N)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:32
User entered 'No (N)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:30
User entered '10 Feb 2021'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:28
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:26
User closed query 'Source indicates 'Not Recovered' please review and reconcile where needed. Please see below regarding LTFU data entry expectations.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:44:24
Query 'Source indicates 'Not Recovered' please review and reconcile where needed. Please see below regarding LTFU data entry expectations.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:40:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:40:16
	(b) (4)	
User opened query 'Source indicates 'Not Recovered' please review and reconcile where needed. Please see below regarding LTFU data entry expectations.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:45:12
User entered 'No (N)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'AE#3 PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:56:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:55:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:55:50
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:34
User closed query 'Although subject was LTFU on 25Feb2021, status of AE was 'not recovered/not resolved' at this time, please review LTFU data entry expectations for Outcome of Unknown and instructions for stop date to make applicable updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:44:33
Query 'Although subject was LTFU on 25Feb2021, status of AE was 'not recovered/not resolved' at this time, please review LTFU data entry expectations for Outcome of Unknown and instructions for stop date to make applicable updates in EDC and/or source.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:41:01
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	21 Apr 2021 14:40:16
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	21 Apr 2021 14:40:16

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:40:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	21 Apr 2021 14:39:23
User opened query 'Although subject was LTFU on 25Feb2021, status of AE was 'not recovered/not resolved' at this time, please review LTFU data entry expectations for Outcome of Unknown and instructions for stop date to make applicable updates in EDC and/or source.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:46:24
User entered '25 Feb 2021'	lynn yauch (b) (4)	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:26
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:44:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:44
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:46
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:48
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:50
User entered 'I'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:51
User entered '03 Feb 2021'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:53
User entered '23 Mar 2021'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:46:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:55
User closed query 'Source states that subject was in ICU on 03-07Feb2021, please review and update in EDC as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:44:53
Query 'Source states that subject was in ICU on 03-07Feb2021, please review and update in EDC as necessary.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 14:41:22
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		21 Apr 2021 14:39:23
User entered '4' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:39:23
Query 'Please clarify if 4 or 5 days within the ICU (03-07Feb2021). Thank you.' canceled (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:02:54
User opened query 'Please clarify if 4 or 5 days within the ICU (03-07Feb2021). Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:02:31
User opened query 'Source states that subject was in ICU on 03-07Feb2021, please review and update in EDC as necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:49:27
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	14 Apr 2021 19:26:38
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:00
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:02
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:03
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:08
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:10
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:44
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:49
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Apr 2021 19:26:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Apr 2021 19:26:38
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:50
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 19:26:57
User entered '0'	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:52
User entered '0'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'AE#3 PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:56:15
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:46:58
User closed query 'Source indicates Not Recovered/Not Resolved, with 25Feb2021 (LTFU date) listed. Please note that per eCCGs V5.0, any LTFU subjects with ongoing AEs / SAEs, status should be listed as 'Unknown.'	(b) (4), (b) (6)	21 Apr 2021 14:44:58
Please review EDC against Source, and make updates as necessary to both as applicable.' (Site from CRA).		
Query 'Source indicates Not Recovered/Not Resolved, with 25Feb2021 (LTFU date) listed. Please note that per eCCGs V5.0, any LTFU subjects with ongoing AEs / SAEs, status should be listed as 'Unknown.'	Lorine Cook (b) (4)	21 Apr 2021 14:41:52
Please review EDC against Source, and make updates as necessary to both as applicable.' answered with 'updated ' (Site from CRA).	(b) (4)	
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 14:39:23
User opened query 'Source indicates Not Recovered/Not Resolved, with 25Feb2021 (LTFU date) listed. Please note that per eCCGs V5.0, any LTFU subjects with ongoing AEs / SAEs, status should be listed as 'Unknown.'	(b) (4), (b) (6)	20 Apr 2021 15:39:41
Please review EDC against Source, and make updates as necessary to both as applicable.' (Site from CRA).		
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:47:54
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:43:54
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:49:01
User entered 'patient admitted to hospital with sepsis. After transfer out of ICU patient complained myalgia, joint pain and unable to ambulate. Extensive work up was done for this prolonged hospitalization. Patient was diagnosed with polyarteritis nodosa felt to be related to chronic hepB and possible cocaine and opioid abuse, treated with steroids and antiviral medication for chronic hepB. Patient discharged from hospital to rehab.'	lynn yauch (b) (4)	14 Apr 2021 19:26:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (11)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:26:38

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Folder: Adverse Events

Form: Adverse Events (12)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:26:53

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:10:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:10:44
Data point term sent to Coder	System	20 Apr 2021 19:09:23
User entered 'UTI'	Lorine Cook (b) (4) (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered 'Yes (Y)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered 'No (N)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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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 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered 'No (N)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '24 Feb 2021'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User entered empty.	System	20 Apr 2021 19:08:57

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered 'No (N)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

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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 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:33
User entered '01 Mar 2021'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User entered empty.	System	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:36
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	Lorine Cook (b) (4)	20 Apr 2021 19:20:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:45
User entered 'No (N)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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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 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:52
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:54
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:56
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:11
User entered 'I'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered '0'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[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 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:43:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:36:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:21
User entered empty.	Lorine Cook (b) (4)	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User entered '0'	System	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:53
User entered '1'	System	20 Apr 2021 19:08:57

US3922080

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:23:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:26:53

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:34:56
Query 'Source indicates multiple medications documented from medical records received after SAEs. Please ensure to update con meds with medications taken for SAEs first and complete source with any other outstanding medications.' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:52:01
User opened query 'Source indicates multiple medications documented from medical records received after SAEs. Please ensure to update con meds with medications taken for SAEs first and complete source with any other outstanding medications.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:09:37
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:19:54
User closed query 'Source indicates new medications started: 3. Losartan 25mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR. 4. Amlodipine 10mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:11:06
Query 'Source indicates new medications started: 3. Losartan 25mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR. 4. Amlodipine 10mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR.' answered with 'There was prior HBP meds that was taken and then stopped these are new conmeds. ' (Site from CRA).	Lorine Cook (b) (4)	06 Nov 2020 19:44:00
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:58:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:23:52

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

Audit	User	Time (GMT)
User opened query 'Source indicates new medications started: 3. Losartan 25mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR. 4. Amlodipine 10mg qd po for hypertension, start date: 21 Oct 2020, ongoing. Not for prophylaxis, not for SAR.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:58:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:42
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:56:40
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	06 Nov 2020 16:53:31 05 Oct 2020 16:49:38

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:55:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:55:22
Data point term sent to Coder	System	05 Oct 2020 16:54:45
User entered 'amlodipine'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'hypertension'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '10'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'mg (mg)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'once daily (QD)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '30 Jun 1993'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '09 Sep 2020'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User entered '804 (804)'	System	05 Oct 2020 16:54:04

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:57:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:57:26
Data point term sent to Coder	System	05 Oct 2020 16:55:46
User entered 'amlodipine'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on HYPERTENSION. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 08:30:09
Query 'Per DM CLR: this Con Med was added/ had dose increased on HYPERTENSION. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Confirm AE added' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:59:10
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on HYPERTENSION. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:02:06
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'hypertension'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '20'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'mg (mg)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'once daily (QD)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:54:52
User closed query 'Per CDM: Please clarify Start Date, since it is prior to the corresponding AE recorded with an Indication of 'Worsening of Hypertension', and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:07:40
Query 'Per CDM: Please clarify Start Date, since it is prior to the corresponding AE recorded with an Indication of 'Worsening of Hypertension', and update as appropriate.' answered with 'CM indication is "hypertension" and does not directly correspond to AE of "worsening of hypertension" as the medication dosage was changed prior to the start date of the AE.' (Site from DM).	lynn yauch (b) (4) (b) (4)	21 Oct 2020 12:34:02
User opened query 'Per CDM: Please clarify Start Date, since it is prior to the corresponding AE recorded with an Indication of 'Worsening of Hypertension', and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:19:22
User entered '09 Sep 2020'	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered '0'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:06:43
User closed query 'source indicates this is no longer ongoing. Stop date of 20 Oct 2020, please review and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:06:38
Query 'source indicates this is no longer ongoing. Stop date of 20 Oct 2020, please review and update EDC as needed.' answered with 'corrected' (Site from CRA).	Lorine Cook (b) (4)	06 Nov 2020 19:38:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 19:37:58
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User opened query 'source indicates this is no longer ongoing. Stop date of 20 Oct 2020, please review and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:54:42
User entered 'Yes (Y)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 00:06:41
DataPoint Un-verified.	Lorine Cook (b) (4)	06 Nov 2020 19:37:58
User entered '20 Oct 2020' reason for change: Per Query Resolution	(b) (4) Lorine Cook (b) (4)	06 Nov 2020 19:37:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered empty.	lynn yauch (b) (4) (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:54:52
User entered 'No (N)'	lynn yauch (b) (4)	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User entered '1'	System	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User entered '1'	System	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:04
User entered '804 (804)'	System	05 Oct 2020 16:54:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 11:37:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:37:05
Data point term sent to Coder	System	12 Nov 2020 15:55:34
Coding entries removed.	lynn yauch (b) (4) (b) (4)	12 Nov 2020 15:55:00
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:41:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:41:20
Data point term sent to Coder	System	06 Nov 2020 19:40:42
User entered 'Losartan'	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:40:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:40:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 19:40:26
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4)	06 Nov 2020 19:40:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:40:16
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 18:56:41
User closed query 'Source notes ' HTN AE #1' please review and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:56:38
Query 'Source notes ' HTN AE #1' please review and update as necessary.' answered with 'updated source ' (Site from CRA).	lynn yauch (b) (4)	05 Feb 2021 13:41:06
	(b) (4)	
User opened query 'Source notes ' HTN AE #1' please review and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:24:28
User entered 'Worsening HYPERTENSION(AE #1)' reason for change: Data Entry Error	lynn yauch (b) (4)	12 Nov 2020 15:55:20
	(b) (4)	
DataPoint Un-verified.	lynn yauch (b) (4)	12 Nov 2020 15:55:00
	(b) (4)	
User entered 'HYPERTENSION(AE #1)' reason for change: Data Entry Error	lynn yauch (b) (4)	12 Nov 2020 15:55:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Hypertension'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '25'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:26:09
User closed query 'Source indicates milligrams, please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:26:07
Query 'Source indicates milligrams, please review and reconcile as needed.' answered with 'updated per source' (Site from CRA).	lynn yauch (b) (4)	10 Nov 2020 22:26:13
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	lynn yauch (b) (4)	10 Nov 2020 22:25:53
	(b) (4)	
User opened query 'Source indicates milligrams, please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:10:19
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'g (g)'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'once daily (QD)'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Oral (ORAL)'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '21 Oct 2020'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '0'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Yes (Y)'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'No (N)'	Lorine Cook (b) (4)	06 Nov 2020 19:40:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:40:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:40:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 19:40:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
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 Nov 2020 20:19:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:19:34
Data point term sent to Coder	System	12 Nov 2020 15:56:36
Coding entries removed.	lynn yauch (b) (4) (b) (4)	12 Nov 2020 15:55:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	07 Nov 2020 00:10:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:42:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:42:20
Data point term sent to Coder	System	06 Nov 2020 19:41:43
User entered 'Amlodipine'	Lorine Cook (b) (4) (b) (4)	06 Nov 2020 19:41:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'No (N)'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:25:06
DataPoint Un-verified.	lynn yauch (b) (4)	12 Nov 2020 15:55:41
	(b) (4)	
User entered 'Worsening HYPERTENSION(AE #1)'	lynn yauch (b) (4)	12 Nov 2020 15:55:41
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Hypertension'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '10'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'mg (mg)'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'once daily (QD)'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Oral (ORAL)'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '21 Oct 2020'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered '0'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered 'Yes (Y)'	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 00:10:17
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:41:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 19:41:43
User entered 'No (N)' reason for change: Data Entry Error	Lorine Cook (b) (4)	06 Nov 2020 19:41:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 19:41:34
User entered empty.	Lorine Cook (b) (4)	06 Nov 2020 19:41:34
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:41:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:41:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 19:41:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 20:44:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 20:44:57
Data point term sent to Coder	System	15 Apr 2021 20:43:29
User entered 'tramadol'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered 'pain'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered '50'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered 'once daily (QD)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:19
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:30:47
User closed query 'Please enter date per source, un-unk-2021.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:30:44
Query 'Please enter date per source, un-unk-2021.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 17:30:16
	(b) (4)	
User entered 'un UNK 2021' reason for change:	Lorine Cook (b) (4)	21 Apr 2021 17:29:59
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User opened query 'Please enter date per source, un-unk-2021.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:28:08
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:34:05
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	21 Apr 2021 17:32:39
User entered '0' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 17:32:39
	(b) (4)	
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	21 Apr 2021 17:29:59
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:45
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:28:34
User entered '1'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:11
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:13
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 17:28:14
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:42:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:42:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:42:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 20:42:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
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: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:51:50
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 Apr 2021 12:51:50
Data point term sent to Coder	System	15 Apr 2021 20:47:32
User entered 'toradol'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 20:47:20

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'pain'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 07:00:38
User entered 'unknown' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 20:52:28
Query 'Data is required. Please complete.' answered with 'medication from hospital records, dose is unknown' (Site from System).	(b) (4)	
	lynn yauch (b) (4)	15 Apr 2021 20:48:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Apr 2021 20:47:20
	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'un UNK 2021' reason for change:	Lorine Cook (b) (4)	21 Apr 2021 17:33:21
Data Entry Error	(b) (4)	
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered '0' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 17:33:21
	(b) (4)	
User entered '1'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:50
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:47:20
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:47:20

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:47:20

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:47:20

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:53:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:53:17
Data point term sent to Coder	System	15 Apr 2021 20:51:36
User entered 'dilaudid'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 20:51:05

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'pain'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 07:00:48
User entered 'unknown' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 20:51:33
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4)	15 Apr 2021 20:51:15
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:51:05
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:55
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:51:05
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:51:05

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:51:05

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:51:05

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:25:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:25:39
Data point term sent to Coder	System	15 Apr 2021 20:55:43
User entered 'lidocaine 5%'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'pain'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'twice daily (BID)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'Transdermal (TRANSDERMAL)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:58
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:55:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 20:55:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:55:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 20:55:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:00:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:00:40
Data point term sent to Coder	System	15 Apr 2021 20:57:45
User entered 'voltaren gel'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 20:57:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'pain'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'Topical (TOPICAL)'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:16:02
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:57:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 20:57:30
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Apr 2021 20:57:30
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:57:23
User entered empty.	lynn yauch (b) (4) (b) (4)	15 Apr 2021 20:57:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:02
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 20:57:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:57:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:57:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 20:57:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:54:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:54:13
Data point term sent to Coder	System	15 Apr 2021 21:02:54
User entered 'gabapentin'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'neuropathy pain'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered '200'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'three times daily (TID)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:55
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:02:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 21:02:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:02:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 21:02:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:38:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	16 Apr 2021 01:38:11
Data point term sent to Coder	System	15 Apr 2021 21:09:01
Coding entries removed.	lynn yauch (b) (4)	15 Apr 2021 21:08:43
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 21:08:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Apr 2021 21:08:33
Data point term sent to Coder	System	15 Apr 2021 21:05:58
User entered 'duloxetine'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'neuropathy pain' reason for change:	lynn yauch (b) (4)	15 Apr 2021 21:08:43
Data Entry Error	(b) (4)	
User entered 'depression'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered '20'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'once daily (QD)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:16:58
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:05:30
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:05:30

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:05:30

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 21:05:30

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:51
Data point term sent to Coder	System	21 Apr 2021 18:58:19
Data point term sent to Coder	System	21 Apr 2021 18:57:18
Coding entries removed.	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 18:56:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:17:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:17:08
Data point term sent to Coder	System	15 Apr 2021 21:15:13
User entered 'xarelto'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:42:16
User closed query 'Source notes AE #4 with correction to AE #11 for UTI. Please review both and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:42:02
Query 'Source notes AE #4 with correction to AE #11 for UTI. Please review both and update as necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 18:57:06
DataPoint Un-verified.	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 18:56:46
User entered 'AE# 11 UTI' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 18:56:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User opened query 'Source notes AE #4 with correction to AE #11 for UTI. Please review both and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:17:54
User entered 'AE# 4 superficial venous thrombosis cepheri vein right UE'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered '20'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	21 Apr 2021 20:42:43
User closed query 'source notes 'po' please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:42:31
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	21 Apr 2021 18:57:49
Query 'source notes 'po' please review and reconcile' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 18:57:36
	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	21 Apr 2021 18:56:46
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 18:56:46
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 18:56:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
	(b) (4), (b) (6)	
User opened query 'source notes 'po' please review and reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:19:12
	(b) (4), (b) (6)	
Query 'source indicates by mouth, review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:18:56
	(b) (4), (b) (6)	
User opened query 'source indicates by mouth, review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:18:41
	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:42:57
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 18:57:49
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 18:57:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:18:50
User entered '15 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:35
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:14
User entered '17 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:19:17
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User entered empty.	System	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User entered empty.	System	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:19
User entered empty.	System	15 Apr 2021 21:15:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 00:35:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 00:35:40
Data point term sent to Coder	System	21 Apr 2021 18:59:20
Coding entries removed.	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 18:58:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Apr 2021 18:20:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:52:41
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 14:52:41
Data point term sent to Coder	System	15 Apr 2021 21:18:21
User entered 'lovenox'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:18:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:32
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:26:52
User closed query 'source notes AE #1 then AE #11, UTI, please review both and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:26:40
Query 'source notes AE #1 then AE #11, UTI, please review both and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 18:59:07
User entered 'AE# 11 UTI' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	21 Apr 2021 18:58:50
User opened query 'source notes AE #1 then AE #11, UTI, please review both and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:20:17
User entered 'AE# 4 SUPERFICIAL VENOUS THROMBOSIS CEPHERI VEIN RIGHT UE'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:39
User entered '40'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:41
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:43
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:45
User entered 'twice daily (BID)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:46
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:27:34
User closed query 'source notes 'po' please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:27:08
Query 'source notes 'po' please review and reconcile.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 18:59:30
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 18:58:50
User opened query 'source notes 'po' please review and reconcile.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:21:22
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:20:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:20:50
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:18:14
User entered 'Other (OTHER)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 21:18:14
	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:18:01
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:27:21
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 18:58:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 18:58:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:20:53
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:57
User entered '17 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:20:59
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:21:01
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:21:04
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:21:06
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:18:01
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 21:18:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:18:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 21:18:01

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIUM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:01:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	21 Apr 2021 20:01:38
Data point term sent to Coder	System	21 Apr 2021 19:03:23
Coding entries removed.	Lorine Cook (b) (4)	21 Apr 2021 19:02:31
DataPoint Verified.	(b) (4)	21 Apr 2021 18:21:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIUM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 21:23:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Apr 2021 21:23:09
Data point term sent to Coder	System	15 Apr 2021 21:21:23
User entered 'bactrium DS'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:21:45
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:37:48
User closed query 'Source notes AE #5 cystitis possibly and UTI AE #11 crossed out, please review and update where needed, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:36:50
Query 'Source notes AE #5 cystitis possibly and UTI AE #11 crossed out, please review and update where needed, thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 19:02:59
User entered 'AE#5 (Cystitis)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 19:02:31
User opened query 'Source notes AE #5 cystitis possibly and UTI AE #11 crossed out, please review and update where needed, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:22:28
User entered 'AE#11 urinary tract infection'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:22:48
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:22:52
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:21:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:21:37
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:20:40
User entered 'puff (PUFF)'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:22:54
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:38:13
Query ' source indicates 'BID' please review and reconcile' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:37:59
User entered 'twice daily (BID)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:37:42
User opened query ' source indicates 'BID' please review and reconcile' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:35:32
User closed query 'source indicates 'BID' please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:35:32
Query 'source indicates 'BID' please review and reconcile.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 19:03:16
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 19:02:31
	(b) (4)	
User opened query 'source indicates 'BID' please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:23:14
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 21:20:40
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:22:59
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:23:34
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:23:37
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:23:42
User entered '24 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:23:45
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:36:33
User closed query 'source indicates stop date of 01Mar2021, please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:35:45
Query 'source indicates stop date of 01Mar2021, please review and update if needed.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 19:05:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 19:02:31
User opened query 'source indicates stop date of 01Mar2021, please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:24:05
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 21:22:38
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:12:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:36:03
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 19:02:31
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 19:02:31
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Lorine Cook (b) (4)	21 Apr 2021 19:02:31
	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:24:06
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Apr 2021 21:22:38
User entered empty; reason for change Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 21:22:38
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Apr 2021 21:22:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:22:06
User entered 'un UNK 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	15 Apr 2021 21:22:06
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:21:37
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	15 Apr 2021 21:21:37
User entered 'Jan ' (non-conformant).	lynn yauch (b) (4)	15 Apr 2021 21:21:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	15 Apr 2021 21:20:40
User entered '01 Mar 2021'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:24:09
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User entered '2'	System	21 Apr 2021 21:37:42
User entered '3'	System	21 Apr 2021 19:02:31
User entered empty.	System	15 Apr 2021 21:20:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User entered '1'	System	21 Apr 2021 19:02:31
User entered empty.	System	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:23
User entered '804 (804)'	System	21 Apr 2021 19:02:31
User entered empty.	System	15 Apr 2021 21:20:40

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:34:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:34:09
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 21:25:30
User entered 'diflucan'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:05
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:12
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:14
User entered '200'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:25:16
User entered 'mg (mg)'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:24:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:18
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:20
User entered 'once daily (QD)'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:22
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:25
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:27
User entered 'unkown'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:43
User entered '22 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:45
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:47
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:51
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:25:53
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:24:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:24:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:24:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 21:24:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:26:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:22:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 01:22:06
Data point term sent to Coder	System	15 Apr 2021 21:27:32
User entered 'cefepime'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:26:23
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'SAE#1 septic shock'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:27:23
User entered 'Other (OTHER)' reason for change:	lynn yauch (b) (4)	15 Apr 2021 21:27:23
Data Entry Error	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Apr 2021 21:27:09
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered '10 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 21:39:48
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 19:07:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 19:07:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:39:37
User closed query 'source does not list end date currently, please review and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:39:25
Query 'source does not list end date currently, please review and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 19:07:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4)	21 Apr 2021 19:07:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:27:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User opened query 'source does not list end date currently, please review and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:26:51
User entered '19 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:11
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:27:09
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:27:09

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:27:09

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:27:09

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:08:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:08:32
Data point term sent to Coder	System	15 Apr 2021 21:29:35
User entered 'vancomycin'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:27:47
User entered 'SAE#1 septic shock'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'Other (OTHER)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'unknown'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered '10 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:01:36
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 19:08:26
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 19:08:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:01:47
User closed query 'source does not indicate a stop date, please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:01:23
Query 'source does not indicate a stop date, please review and reconcile as needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 19:08:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4)	21 Apr 2021 19:08:26
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:28:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User opened query 'source does not indicate a stop date, please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:28:08
User entered '19 Feb 2021'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:30
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:28:48
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:28:48

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:28:48

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 21:28:48

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:28:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 00:33:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 00:33:10
Data point term sent to Coder	System	15 Apr 2021 21:32:37
User entered 'aspirin'	lynn yauch (b) (4) (b) (4)	15 Apr 2021 21:31:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:44
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'SAE#3 polyarteritis nodosa'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered '81'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'mg (mg)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'once daily (QD)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'un UNK 2021'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered '0'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'Yes (Y)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered empty.	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:28:59
User entered 'No (N)'	lynn yauch (b) (4)	15 Apr 2021 21:31:57
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:31:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 21:31:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 21:31:57

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:29:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:14:35
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 08:14:35
Data point term sent to Coder	System	16 Apr 2021 17:08:00
User entered 'prednisone'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered 'SAE#3 (polyarteritis nodosa)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered '125'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered 'mg (mg)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered 'once daily (QD)'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:09:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:23
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:48
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:48
User entered '03 Mar 2021' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:08:48
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:43
User entered '04 Mar 2021' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:08:43
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:29
User entered 'UN UNK 2021' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:08:29
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:08:22
User entered 'un Mar 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 17:08:22
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:07:26
User entered '03 Mar 2021'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:48
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:29:31
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	16 Apr 2021 17:10:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:09:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:26
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:10:31
User entered '11 Mar 2021' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:10:31
User entered empty.	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:29:29
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User entered '1'	System	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User entered '1'	System	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:32
User entered '804 (804)'	System	16 Apr 2021 17:07:26

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:30:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:14:35
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 08:14:35
Data point term sent to Coder	System	16 Apr 2021 17:11:07
User entered 'prednisone'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'SAE#3 (polyarteritis nodosa)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered '80'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'mg (mg)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'once daily (QD)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:17:15
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:10:10
User entered '12 Mar 2021'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:10:10
User entered '16 Mar 2021'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:30:14
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User entered '1'	System	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User entered '1'	System	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:34
User entered '804 (804)'	System	16 Apr 2021 17:10:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses".' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 06:20:03
Query 'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses".' answered with 'medication is correct per medical records, subject has been LTFU' (Site from DM).	lynn yauch (b) (4)	26 Apr 2021 19:09:51
User opened query 'Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses".' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 00:37:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:14:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 08:14:36
Data point term sent to Coder	System	16 Apr 2021 17:13:10
User entered 'prednisone'	lynn yauch (b) (4)	16 Apr 2021 17:12:27

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'SAE#3 (polyarteritis nodosa)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered '60'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'mg (mg)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'once daily (QD)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:17:31
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	16 Apr 2021 17:12:27
User entered '17 Mar 2021'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:12:27

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:31:02
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:12:27
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:12:27

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:12:27

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:12:27

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:54:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:54:28
Data point term sent to Coder	System	16 Apr 2021 17:14:11
User entered 'gabapentin'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:33
User entered 'SAE#3 (polyarteritis nodosa)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:09
User entered '400'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered 'mg (mg)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:37
User entered 'three times daily (TID)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:40
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:42
User entered 'un UNK 2021'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:34:55
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:14:03
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 17:14:03

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:14:03

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:14:03

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:07
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)	16 Apr 2021 17:32:05
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 17:32:05
Data point term sent to Coder	System	16 Apr 2021 17:18:16
User entered 'Norco'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'SAE#3 (polyarteritis nodosa)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'UnKNOWN' reason for change: Data Entry Error	lynn yauch (b) (4)	19 Apr 2021 19:20:23
	(b) (4)	
User entered 'uunknown'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:35:25
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	19 Apr 2021 19:20:23
User entered 'Other (OTHER)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:20:23
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	16 Apr 2021 17:18:10
User entered 'puff (PUFF)'	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:18:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'unknown'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'Other (OTHER)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'unknown'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:12
User entered 'un UNK 2021'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:25
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:18:10
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:18:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:18:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:18:10

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:32:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	16 Apr 2021 17:32:52
Data point term sent to Coder	System	16 Apr 2021 17:25:24
User entered 'albuterol'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered 'chronic obstructive pulmonary disease'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:42
User entered '2.0'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:45
User entered 'mg (mg)'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:40
User entered 'as needed (PRN)'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:48
User entered 'un UNK 2021'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:36:24
User entered empty.	lynn yauch (b) (4) (b) (4)	16 Apr 2021 17:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:35:51
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE, PRODUCTSYNONYM: ATROVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 08:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 08:07:29
Data point term sent to Coder	System	16 Apr 2021 17:27:25
User entered 'Atrovent 0.02%'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'chronic obstructive pulmonary disease'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered '500'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:03:56
User closed query 'source notes 500 mg, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:03:45
Query 'source notes 500 mg, please review and reconcile.' answered with 'updated source' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:44:58
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:37:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User opened query 'source notes 500 mg, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:37:17
User entered 'ug (ug)'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:38
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'un UNK 2021'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:37:51
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:26:55
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:26:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:26:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:26:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 17:42:40
User entered 'fluticasone'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:17
User entered 'chronic obstructive pulmonary disease'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'unknown'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'Other (OTHER)'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:06:14
User closed query 'source notes '30 mL' however, not typical dose, please review source and EDC to determine where update is necessary and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:06:02
Query 'source notes '30 mL' however, not typical dose, please review source and EDC to determine where update is necessary and update accordingly.' answered with 'corrected' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:52:07
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:37
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User opened query 'source notes '30 mL' however, not typical dose, please review source and EDC to determine where update is necessary and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:38:47
User entered 'unknown'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'twice daily (BID)'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:09
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'un UNK 2021'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered '0'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered empty.	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:39:31
User entered 'No (N)'	lynn yauch (b) (4)	16 Apr 2021 17:42:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 17:42:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:42:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:42:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE BITARTRATE, PRODUCTSYNONYM: LEVOPHED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:24
Data point term sent to Coder	System	19 Apr 2021 19:36:09
User entered 'levophed(8mg)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:35:21

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered 'SAE#1(septic shock)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:31
User entered '250'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:33
User entered 'mL (mL)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:15
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:38
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:40:53
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:35:21
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:35:21

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:35:21

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:35:21

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: PIPERACILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:05:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:05:37
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:39:13
User entered 'piperacillin'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'SAE#1 (septic shock)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered '3.375'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:41:36
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:38:13
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 19:38:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:38:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 19:38:13

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:46:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:16:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:16:47
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 22:09:36
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 22:09:10
	(b) (4)	
Coding entries removed.	Lorine Cook (b) (4)	21 Apr 2021 22:09:10
	(b) (4)	
User entered 'Ceftriaxone' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 22:09:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:41:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:38:05
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:38:05
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:41:14
User entered 'ceftiaxone'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'SAE#1(septic shock)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:05
User entered '2'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:08
User entered 'g (g)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:22
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:41:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:41:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:41:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 19:41:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:07:34
User closed query 'source notes lactate ringer, review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:07:19
Query 'source notes lactate ringer, review and reconcile.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:36:40
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:50:11
User opened query 'source notes lactate ringer, review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:42:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 19:46:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:46:18
User entered 'lactated ringer'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:12
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:20
User entered 'hydration'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:57
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:44:59
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:02
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:04
User entered 'other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:25
User entered 'continuous'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:43
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:06
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:47
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:08
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:11
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:13
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:45:15
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:45:42
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:45:42

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:45:42

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 19:45:42

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:47:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE, PRODUCTSYNONYM: VITAMIN B1 [THIAMINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:12:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:12:00
Data point term sent to Coder	System	19 Apr 2021 19:47:22
User entered 'thiamine(vitamin B-1)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:08:47
User closed query 'per eCCGs, supplements are taken prophylatic, please review current selection within EDC and source and determine if should be updated to Yes, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:08:32
Query 'per eCCGs, supplements are taken prophylatic, please review current selection within EDC and source and determine if should be updated to Yes, thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:34:36
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:34:13
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 18:50:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User opened query 'per eCCGs, supplements are taken prophylatic, please review current selection within EDC and source and determine if should be updated to Yes, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:47:28
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:47:47
User entered 'supplement'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered '100'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:47:18

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:50:08
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:47:18
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:47:18

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:47:18

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 19:47:18

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:52:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 19:52:43
Data point term sent to Coder	System	19 Apr 2021 19:51:26
User entered 'trazadone'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:50:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'insomnia'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered '50'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'three times daily (TID)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:50:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:01:58
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 19:50:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 19:50:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 19:50:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 19:50:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:02:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:24
Data point term sent to Coder	System	19 Apr 2021 20:02:40
User entered 'lidocane'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'tongue lesion biopsy'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'once (ONCE)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered '08 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered '08 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:02:38
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User entered empty.	System	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User entered empty.	System	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:24
User entered empty.	System	19 Apr 2021 20:02:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
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) (b) (4)	19 Apr 2021 20:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:05:35
Data point term sent to Coder	System	19 Apr 2021 20:04:42
User entered 'losartan HCTZ'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:03:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'hypertension'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered '50/12.5'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:55
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:03:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:03:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:03:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:03:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:06:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:06:46
Data point term sent to Coder	System	19 Apr 2021 20:05:43
User entered 'ondansetron'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'nausea/vomiting'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered '4'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'as needed (PRN)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:03:58
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:05:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:05:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:05:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:05:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:07:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 20:07:31
Data point term sent to Coder	System	19 Apr 2021 20:06:43
User entered 'naproxen'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'pain'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered '500'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered '24 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:04:22
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:06:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:06:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:06:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:06:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE, PRODUCTSYNONYM: CHLORTHALIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:09:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:09:38
Data point term sent to Coder	System	19 Apr 2021 20:08:45
User entered 'chlorthalidone'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:07:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'hypertension'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered '25'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:05:41
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:07:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:07:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:07:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:07:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:10:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:10:44
Data point term sent to Coder	System	19 Apr 2021 20:09:52
User entered 'famotidine'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'Gerd'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered '20'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:05
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:09:47
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:09:47

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:09:47

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:09:47

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 20:12:32
Data point term sent to Coder	System	19 Apr 2021 20:11:53
User entered 'fluoxetine'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'depression'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered '20'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:28
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:11:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:11:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:11:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:11:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:24
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:24
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 20:16:01
User entered 'lidocane 2%'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'AE#10(left dorsal tongue ulcerative lesion)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered '15'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'mL (mL)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'as needed (PRN)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'oral rinse'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:06:57
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:04:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:04:15
Data point term sent to Coder	System	19 Apr 2021 20:21:06
User entered 'methocarbamol'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'SAE#3(polyarteritis nodosa)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:20:43

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered '500'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'three times daily (TID)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:07:18
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:20:43
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 20:20:43

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:20:43

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:20:43

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:09:56
User closed query 'Source notes 'Spriva' please review both and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:09:44
Query 'Source notes 'Spriva' please review both and update where necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:28:35
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:51
User opened query 'Source notes 'Spriva' please review both and update where necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:08:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 20:23:11
User entered 'spiriva'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'chronic obstructive pulmonary disease'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered '16'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'ug (ug)'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'four times daily (QID)'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:08:02
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:22:36
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:22:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:22:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:22:36

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:26:39
Data point term sent to Coder	System	19 Apr 2021 20:25:15
User entered 'senna'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:01
User entered 'constipation'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered '17.2'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:07
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:13
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:10:33
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:25:14
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:25:14

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
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.	Coder Import (b) (4)	19 Apr 2021 20:27:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:27:43
Data point term sent to Coder	System	19 Apr 2021 20:27:18
User entered 'multivitamin'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'supplement'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:11:41
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:26:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:26:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:26:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:26:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:29:48
Data point term sent to Coder	System	19 Apr 2021 20:28:21
User entered 'lorazepam'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:08
User entered 'anxiety'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered 'I'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:06
User entered 'as needed (PRN)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:12
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:33
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:13
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:28:02
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:28:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:28:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:28:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:58
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)	20 Apr 2021 09:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:53:45
Data point term sent to Coder	System	19 Apr 2021 20:30:24
User entered 'fentanyl(1mcg)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered 'pain'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:59
User entered 'I'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:13:01
User entered 'mL (mL)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:57
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:12:55
User entered 'Intramuscular (INTRAMUSCULAR)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:13:04
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:22:49
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:30:16
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:30:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:30:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:30:16

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:32:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 20:32:35
Data point term sent to Coder	System	19 Apr 2021 20:31:24
User entered 'metoprolol'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'hypertension'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered '50'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:57
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:31:22
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:31:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:31:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:31:22

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:35:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:35:35
Data point term sent to Coder	System	19 Apr 2021 20:34:32
User entered 'Polyethylene glycol'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'constipation'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered '17'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'g (g)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:19
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:33:58
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:33:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:33:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:33:58

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:22:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:22:46
Data point term sent to Coder Coding entries removed.	System Lorine Cook (b) (4)	21 Apr 2021 21:23:53 21 Apr 2021 21:22:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:18:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
Data point term sent to Coder User entered 'nystatin powder'	System lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:37:49 19 Apr 2021 20:36:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'SAE#3(polyarteritis nodosa)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:12:27
User closed query 'Source notes route as topical, review and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:12:12
Query 'Source notes route as topical, review and update as necessary.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:23:34
	(b) (4)	
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:22:53
	(b) (4)	
User opened query 'Source notes route as topical, review and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:19:16
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:18:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:18:51
	(b) (4)	
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:18:51
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:36:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:36:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:36:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:36:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:19:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:39:43
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Apr 2021 20:39:43
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	19 Apr 2021 20:38:50
User entered 'atorvastatin'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:19:38
User entered 'hyperlipidemia'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:19:36
User entered '40'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:23:35
	(b) (4), (b) (6)	
User closed query 'source notes 'QD' review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:23:23
Query 'source notes 'QD' review and reconcile as needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:22:16
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:22:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:20:36
	(b) (4), (b) (6)	
User opened query 'source notes 'QD' review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:20:01
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:36
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:38:23
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:22:00
User entered empty.	System	19 Apr 2021 20:38:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:22:00
User entered empty.	System	19 Apr 2021 20:38:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 21:22:00
User entered empty.	System	19 Apr 2021 20:38:23

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:20:52
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: CARBAMIDE PRODUCTS, PRODUCT: UREA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:12:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	20 Apr 2021 10:12:28
Data point term sent to Coder	System	19 Apr 2021 20:48:04
User entered 'urea cream 10%'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'myxedema of hands'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:21:20
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	19 Apr 2021 20:48:16
User entered 'Other (OTHER)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:48:16
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	19 Apr 2021 20:47:46
User entered 'puff (PUFF)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:47:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:06
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:08
User entered 'Topical (TOPICAL)'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:20
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:47:46
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 20:47:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:47:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:47:46

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ENTECAVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 20:50:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 20:50:54
Data point term sent to Coder	System	19 Apr 2021 20:50:06
User entered 'entecavir'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'Hepatitis B'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered '0.5'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered '25 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:49:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:21:50
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:49:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:49:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 20:49:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 20:49:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:22:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:54:39
Data point term sent to Coder	System	19 Apr 2021 20:54:17
User entered 'fluconazole'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'AE#11(urinary tract infection'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered '200'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered '22 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:18:35
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	19 Apr 2021 20:54:02
User entered '08 Mar 2021'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:22:35
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User entered empty.	System	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User entered empty.	System	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:55
User entered empty.	System	19 Apr 2021 20:54:02

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:54:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	22 Apr 2021 05:54:10
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:20:18
User closed query 'source indicates 'Meropenum' please review and update where needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:20:06
Data point term sent to Coder	System	21 Apr 2021 21:20:50
Query 'source indicates 'Meropenum' please review and update where needed.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:20:42
Coding entries removed.	Lorine Cook (b) (4)	21 Apr 2021 21:19:57
User entered 'Meropenem' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:19:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:12
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User opened query 'source indicates 'Meropenum' please review and update where needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:23:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:04:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	20 Apr 2021 10:04:15
Data point term sent to Coder	System	19 Apr 2021 20:58:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'meropenem'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'AE#11 (urinary tract infection)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'l'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'g (g)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:23:43
User entered 'four times daily (QID)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:23:51
User entered '25 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
Query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:18:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:23:50
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	19 Apr 2021 20:57:55
User entered '01 Mar 2021'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:24:08
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User entered '4'	System	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User entered '1'	System	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:56:58
User entered '804 (804)'	System	19 Apr 2021 20:57:55

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 21:19:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 21:19:37
Data point term sent to Coder Coding entries removed.	System Lorine Cook (b) (4)	21 Apr 2021 21:18:49 21 Apr 2021 21:18:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:24:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:00:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:00:51
Data point term sent to Coder User entered 'coreg'	System lynn yauch (b) (4) (b) (4)	19 Apr 2021 20:59:24 19 Apr 2021 20:59:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:24:24
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:24:26
User entered 'hypertension'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:24:31
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:21:40
User closed query 'source notes 'po' please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:21:27
Query 'source notes 'po' please review and reconcile as needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:18:35
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:18:15
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User opened query 'source notes 'po' please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:24:53
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:21:52
DataPoint Un-verified.	Lorine Cook (b) (4)	21 Apr 2021 21:18:15
	(b) (4)	
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	21 Apr 2021 21:18:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:25:54
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 20:59:19
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:59:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:59:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 20:59:19

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:04
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 Apr 2021 10:03:04
Data point term sent to Coder	System	19 Apr 2021 21:01:26
User entered 'lasix'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:14
User entered 'acute renal failure'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:26:42
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	21 Apr 2021 14:54:01
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	21 Apr 2021 14:54:01
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	19 Apr 2021 21:01:08
User entered 'puff (PUFF)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:17
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:21
User entered '07 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:26:42
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User entered empty.	System	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User entered empty.	System	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:03
User entered empty.	System	19 Apr 2021 21:01:08

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:25:37
User closed query 'Source is hard to determine what is correct spelling, appears to be ditazem in chart; please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:25:25
Query 'Source is hard to determine what is correct spelling, appears to be ditazem in chart; please review and reconcile as needed.' answered with 'chart updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:16:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:29:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User opened query 'Source is hard to determine what is correct spelling, appears to be ditazem in chart; please review and reconcile as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:28:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:52:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 21:04:30
User entered 'Diltiazem'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:27:23
User entered 'atrial fibrillation'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:27:09
User entered '20'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:27:13
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:27:19
User closed query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Apr 2021 21:04:07
User entered 'unknown' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:04:07
User opened query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Apr 2021 21:03:32
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:03:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 21:04:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 21:04:07
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	19 Apr 2021 21:04:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 21:03:32
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:03:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:28:41
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:03:32
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:03:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:03:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:03:32

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:29:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:23:47
Data point term sent to Coder	System	19 Apr 2021 21:06:37
User entered 'amiodarone'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'atrial fibrillation'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:26
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:32
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:29
User entered '05 Feb 2021'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:45
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User entered empty.	System	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User entered empty.	System	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:57:08
User entered empty.	System	19 Apr 2021 21:06:34

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:30:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:09:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 21:09:39
Data point term sent to Coder	System	19 Apr 2021 21:08:40
User entered 'albumin'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'acute renal failure'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:29:59
User entered 'Intravenous (INTRAVENOUS)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:05
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:26:49
User closed query 'Please update per end date, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:26:38
Query 'Please update per end date, thank you.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:15:15
DataPoint Un-verified.	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 21:14:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 21:14:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User opened query 'Please update per end date, thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:59:48
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	21 Apr 2021 21:14:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:03
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Apr 2021 21:08:33
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:08:33
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:30:16
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User entered empty.	System	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User entered empty.	System	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:22
User entered empty.	System	19 Apr 2021 21:08:33

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID, PRODUCTSYNONYM: FOLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 20:04:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 20:04:41
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 21:11:43
User entered 'folate/folic acid'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'anemia'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:31:11
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Apr 2021 21:11:29
User entered 'unknown' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:11:29
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Apr 2021 21:10:56
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:10:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'unknown (UNKNOWN)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'unknown'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:10:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:11
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:10:56
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:10:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:10:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:10:56

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:21:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:21:56
Data point term sent to Coder	System	19 Apr 2021 21:14:46
User entered 'aripirazole'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'schizo affective disorder'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered '20'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'once daily (QD)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 22:28:04
User closed query 'source currently blank for route, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:27:52
Query 'source currently blank for route, please review and reconcile.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:13:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:32:14
User opened query 'source currently blank for route, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:32:13
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:31:15
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:14:12
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:14:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:14:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 21:14:12

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:32:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 21:16:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Apr 2021 21:16:32
Data point term sent to Coder	System	19 Apr 2021 21:15:47
User entered 'buspirone'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:32:37
User entered 'anxiety'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered '10'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered 'mg (mg)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 21:24:26
User closed query 'source indicates 'BID' please review and update where needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:24:12
Query 'source indicates 'BID' please review and update where needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:12:52
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Lorine Cook (b) (4)	21 Apr 2021 21:12:31
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:32
	(b) (4), (b) (6)	
User opened query 'source indicates 'BID' please review and update where needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:33:17
User entered 'three times daily (TID)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:22
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered empty.	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:32
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:15:31
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 21:12:31
User entered '3'	System	19 Apr 2021 21:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 21:15:31

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:22:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 09:22:39
Data point term sent to Coder	System	19 Apr 2021 21:18:54
User entered 'Chlorhexidine Gluconate 0.12%'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:33:51
User entered 'AE#10 (left dorsal tongue ulcerative lesion)'	lynn yauch (b) (4) (b) (4)	19 Apr 2021 21:18:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:53
User entered '15'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'mL (mL)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:56
User entered 'twice daily (BID)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'Other (OTHER)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:33:58
User entered 'oral rinse'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'un UNK 2021'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered '0'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'Yes (Y)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered empty.	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 21:55:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:34:09
User entered 'No (N)'	lynn yauch (b) (4)	19 Apr 2021 21:18:49
	(b) (4)	

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 21:18:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 21:18:49

US3922080

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 10 Jun 2021 10:23:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 21:18:49

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:23:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:55:14
User closed query 'Please add missing con procedure, currently 23/24 procedures reflected in EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:35:34
Query 'Please add missing con procedure, currently 23/24 procedures reflected in EDC. Thank you.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	14 Apr 2021 14:18:17
User opened query 'Please add missing con procedure, currently 23/24 procedures reflected in EDC. Thank you.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:51:53
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 21:06:59
DataPoint Un-verified.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
Signature has been broken.	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	23 Mar 2021 19:48:14
User signature succeeded.	(b) (4)	
DataPoint Verified.	lynn yauch (b) (4)	23 Mar 2021 19:48:14
User entered 'No (N)'	(b) (4)	
	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 21:25:23
	(b) (4)	
	lynn yauch (b) (4)	11 Nov 2020 15:39:28
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:06:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered '03 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 19:54:03
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:06:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'XR chest, 1 view'	lynn yauch (b) (4)	23 Mar 2021 19:54:03
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:43:52
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:05:07
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:37:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:16:17
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:54:03

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:06:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	23 Mar 2021 19:54:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:19
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '04 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:55:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:19
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:06:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'CT Brain w/o IV contrast'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:55:23

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:44:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:57:10
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:39:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:00:40
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:55:23

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:19
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:55:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:15
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '04 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:56:10
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:15
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'XR left hand, 3 or more views'	lynn yauch (b) (4)	23 Mar 2021 19:56:10
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:15
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:44:09
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:05:16
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:40:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:16:34
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:56:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:15
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:56:10
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:11
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '04 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:57:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:11
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'XR right hand, 3 or more views'	lynn yauch (b) (4)	23 Mar 2021 19:57:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:44:17
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:07:54
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:41:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:17:43
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:57:03

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:11
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:57:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:08
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:57:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:08
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'CT cervical spine, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 19:57:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:44:25
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 04:26:16
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:41:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:11:34
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:57:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:08
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:57:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:58:33
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'CT lower extremity right, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 19:58:33
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:05
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:44:42
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:00:20
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:49:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:06:18
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:58:33

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:14:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:06:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:58:33
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:24
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:59:18
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:24
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'CT upper extremity right, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 19:59:18
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:45:12
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:02:07
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:50:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:10:23
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 19:59:18

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:24
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 19:59:18
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:29
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:00:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:29
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'CT upper extremity left, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 20:00:05
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:45:25
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:01:50
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:50:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Query 'er DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:10:12
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:10:08

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User opened query 'er DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Michele Reynolds (b) (4)	07 Apr 2021 11:08:16 24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:00:05

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:29
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:46
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:00:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:34
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:00:55
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:34
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'CT lower extremity left, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 20:00:55
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:45:30
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:59:54
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:51:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:04:38
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:00:55

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:34
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:00:55
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:39
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:05:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:02:31

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:39
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'CT chest, w/o IV contrast'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:02:31
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:45:43
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:58:34
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:52:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:02:26
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:02:31

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:39
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:02:31
	(b) (4)	

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:43
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:04:55
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:04:34

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:43
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:04:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'CT abdomen/pelvis, w/o IV contrast'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:04:34

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:45:48
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 04:26:06
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:53:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:13:03
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:04:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:43
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:05:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:04:34
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:04:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:05:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:50:19
User closed query 'Please review spelling in EDC and source, and clarify if should be 'Thoracic.' ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:50:15
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
Query 'Please review spelling in EDC and source, and clarify if should be 'Thoracic.' ' answered with 'Confirm corrected spelling in source & EDC' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:56:28
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 16:55:38
User entered 'CT THORACIC SPINE, W/O IV CONTRAST' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:55:38
User opened query 'Please review spelling in EDC and source, and clarify if should be 'Thoracic.' ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:04:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:04:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'CT thoracic spine, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 20:05:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:50:22
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:01:32
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:56:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:07:38
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:05:32

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:04:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:05:32

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:51
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '05 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:07:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:51
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'CT lumbar spine, w/o IV contrast'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:07:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:51
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:46:01
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 04:25:40
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:58:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:18:11
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:07:05

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:51
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:07:05
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:55
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered '07 Feb 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	23 Mar 2021 20:12:27
	(b) (4)	
User entered '05 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 20:07:48
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:55
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'XR Chest 1 view'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:07:48
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:46:06
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:04:01
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:00:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:14:26
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:07:48

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:55
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:04:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:07:48
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:58
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:03:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '07 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:08:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:58
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:03:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'MAXiLLOFACIAL CT, W/O IV CONTRAST' reason for change: Data Entry Error	lynn yauch (b) (4)	23 Mar 2021 20:09:05
	(b) (4)	
User entered 'macillofacial CT, w/o IV contrast'	lynn yauch (b) (4)	23 Mar 2021 20:08:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:46:20
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:02:30
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:02:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:10:43
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:08:42

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:20:58
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:03:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:08:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:50:36
User closed query 'source indicates date as 08Feb2021, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:50:33
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with the AE# 4 (08 FEB 2021 - ongoing). Please review and reconcile date of procedure or clarify as necessary. (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 04:24:12
Query 'source indicates date as 08Feb2021, please review and reconcile.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	08 Apr 2021 22:26:39
Query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with the AE# 4 (08 FEB 2021 - ongoing). Please review and reconcile date of procedure or clarify as necessary. answered with 'updated per query' (Site from DM).	lynn yauch (b) (4)	08 Apr 2021 22:25:21
User entered '08 Feb 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Apr 2021 22:24:58
User opened query 'source indicates date as 08Feb2021, please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:49:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with the AE# 4 (08 FEB 2021 - ongoing). Please review and reconcile date of procedure or clarify as necessary. (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:19:16

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered '07 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 20:10:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:53:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'US doppler venous DVT lower extremity bilateral'	lynn yauch (b) (4)	23 Mar 2021 20:10:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:50:45
User closed query 'Please associate with applicable AE / SAE. Source notes 'AE #1' which is worsening hypertension, however, there is also, SAE (AE #2) per source, which is 'Septic Shock.' Likely need to update EDC and source to associate with SAE noted above.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:50:43
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:02:53
Query 'Please associate with applicable AE / SAE. Source notes 'AE #1' which is worsening hypertension, however, there is also, SAE (AE #2) per source, which is 'Septic Shock.' Likely need to update EDC and source to associate with SAE noted above.' answered with 'indication=AE#4, updated source per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:28:10
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=AE#4, source updated' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:27:39
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 21:03:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:53:07
User opened query 'Please associate with applicable AE / SAE. Source notes 'AE #1' which is worsening hypertension, however, there is also, SAE (AE #2) per source, which is 'Septic Shock.' Likely need to update EDC and source to associate with SAE noted above.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:51:53

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:11:13
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:10:47

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:53:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:10:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:58:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '08 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:11:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:58:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'US doppler venous DVT upper extremity right'	lynn yauch (b) (4)	23 Mar 2021 20:11:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:46:56
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:03:03
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=AE#4, source updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:29:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:11:24
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:11:47

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:05
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:02:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:11:47
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:02
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered '10 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:17:58
DataPoint activated with code reason code Data required.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:16:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 17:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:02
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered 'XR Chest 1 view'	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:17:58
DataPoint activated with code reason code Data required.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:16:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 17:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:02
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered 'Adverse Event (AE)'	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:17:58
DataPoint activated with code reason code Data required.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:16:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 17:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:09
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:02
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	14 Apr 2021 14:17:58
	(b) (4)	
DataPoint activated with code reason code Data required.	lynn yauch (b) (4)	14 Apr 2021 14:16:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Apr 2021 17:13:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:15
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:30:30
User closed query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review date against EDC and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:30:07
Query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review date against EDC and update as needed.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:58:30
Signature has been broken.	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 21:57:50
User entered '20 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 21:57:50
User opened query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review date against EDC and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:51:30
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:11
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:39
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:56
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:57:07
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:48:41
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '10 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:13:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:15
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 22:30:41
User closed query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 22:30:19
Query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review and update as needed.' answered with 'updated' (Site from CRA).	Lorine Cook (b) (4)	21 Apr 2021 21:58:49
Signature has been broken.	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 21:57:50
User entered "XR right ankle, 2 views" reason for change: Data Entry Error	(b) (4)	
	Lorine Cook (b) (4)	21 Apr 2021 21:57:50
User opened query 'Source notes #20 'XR right ankle, 2 views' on 20Feb2021, please review and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:51:08
Query 'Source notes #20 'XR right ankle, 2 views' on 10Feb2021, please review and update as needed.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:50:57
User opened query 'Source notes #20 'XR right ankle, 2 views' on 10Feb2021, please review and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:49:28
Query 'Duplicate entry - please remove all data and inactivate log line.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:48:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:54
User opened query 'Duplicate entry - please remove all data and inactivate log line.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:47:50
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:57:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:48:41
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'XR chest, 1 view'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:13:31

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:15
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:30
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:47:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:49:58
User closed query 'Please clarify and specify appropriate AE and/or SAE should be associated with. Source notes 'AE #1,' however, date of occurrence is likely associated with recent SAE 'Septic shock' - please review EDC and source for all con procedures and ensure to update indication to specify appropriate number of adverse event.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:49:57
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:03:25
Query 'Please clarify and specify appropriate AE and/or SAE should be associated with. Source notes 'AE #1,' however, date of occurrence is likely associated with recent SAE 'Septic shock' - please review EDC and source for all con procedures and ensure to update indication to specify appropriate number of adverse event.' answered with 'indication =SAE#1' (Site from CRA).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:31:29
Query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Confirm Correct indication is AE#1 (worsening hypertension); however, drop down box does not allow for additional information.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:23:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Please clarify and specify appropriate AE and/or SAE should be associated with. Source notes 'AE #1,' however, date of occurrence is likely associated with recent SAE 'Septic shock' - please review EDC and source for all con procedures and ensure to update indication to specify appropriate number of adverse event.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:58:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:48:41
User opened query 'Per DM : Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Michele Reynolds (b) (4)	07 Apr 2021 11:13:33 24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:13:31

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:15
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:49:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:00
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:57:11
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:48:41
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	lynn yauch (b) (4)	23 Mar 2021 20:13:31
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:56:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '20 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 20:14:20

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:56:21
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'XR left ankle, 2 views'	lynn yauch (b) (4)	23 Mar 2021 20:14:20

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:04:33
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=AE#8, degenerative joint disease R-ankle/R-knee' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:34:12
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:56:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:15:05
Query 'query issued as Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:14:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
User opened query 'query issued as Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4) Michele Reynolds (b) (4) (b) (4)	07 Apr 2021 11:14:48 24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:14:20

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:18
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:47
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:56:23
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	lynn yauch (b) (4)	23 Mar 2021 20:14:20

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:22
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:53:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '20 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:16:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:22
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:53:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'XR tibia fibula right, 2 views'	lynn yauch (b) (4)	23 Mar 2021 20:16:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:53
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:08:15
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=AE#8 degenerative joint disease R-ankle/R-knee' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:34:56
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:56:02
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:53:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:18:01
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:16:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:22
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:53:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:16:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered '20 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 20:16:53
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'XR right knee, 2 or less views'	lynn yauch (b) (4)	23 Mar 2021 20:16:53
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:08:29
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=AE#8 degenerative joint disease R-ankle/R-knee' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:35:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:18:10
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:16:53

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:25
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:02
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	23 Mar 2021 20:16:53
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:30
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:53:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered '21 Feb 2021'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:17:41
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:30
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:53:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'XR chest, 1 view'	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:17:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:30
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:06
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:04:47
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'indication=SAE#1' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 22:36:26
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 20:55:42
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:53:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:16:00
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:17:41

US3922080

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:30
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:53:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	23 Mar 2021 20:17:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:23:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:16
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered '08 Feb 2021'	lynn yauch (b) (4)	23 Mar 2021 20:18:36
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:23:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:16
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered 'biopsy left dorsal tongue ulcerative lesion'	lynn yauch (b) (4)	23 Mar 2021 20:18:36
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:23:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:16
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Apr 2021 22:59:11
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:49:03
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
User entered 'Adverse Event (AE)'	(b) (4)	
	lynn yauch (b) (4)	23 Mar 2021 20:18:36
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 10:23:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:21:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:52:16
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:49:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 20:48:52
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 13:46:39
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	23 Mar 2021 20:18:36
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:23:52

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:38
User entered '02 Oct 2020'	lynn yauch (b) (4)	15 Jan 2021 16:02:17
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:23:52

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:38
User entered 'AE (specify) (ADVERSE EVENT)'	lynn yauch (b) (4)	15 Jan 2021 16:02:17
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:23:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 13:44:29
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:01:00
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4)	05 Mar 2021 19:49:07
DataPoint Un-verified.	lynn yauch (b) (4)	05 Mar 2021 19:48:45
Signature has been broken.	lynn yauch (b) (4)	05 Mar 2021 19:48:45
User entered 'AE #1' reason for change: Data Entry Error	lynn yauch (b) (4)	05 Mar 2021 19:48:45
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:26:12
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:40:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:59:38
Query 'Per CDM: Primary reason for dosing discontinuation is mentioned as 'AE (specify)'. Please mention the AE number in If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:28:50
User opened query 'Per CDM: Primary reason for dosing discontinuation is mentioned as 'AE (specify)'. Please mention the AE number in If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:33:42

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:23:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'Sub-I withheld 2nd dose due to AE'	lynn yauch (b) (4) (b) (4)	15 Jan 2021 16:02:17

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
	(b) (4)	
User entered '25 Feb 2021'	Lorine Cook (b) (4)	13 Apr 2021 21:39:33
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
	(b) (4)	
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Lorine Cook (b) (4)	13 Apr 2021 21:39:33
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
	(b) (4)	
User entered empty.	Lorine Cook (b) (4)	13 Apr 2021 21:39:33
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered empty.	Lorine Cook (b) (4)	13 Apr 2021 21:39:33

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
User entered empty.	Lorine Cook (b) (4)	13 Apr 2021 21:39:33

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
	(b) (4)	
User entered empty.	Lorine Cook (b) (4)	13 Apr 2021 21:39:33
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:23:52

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:27:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:33:07
User signature succeeded.	Michele Reynolds (b) (4)	14 Apr 2021 17:15:36
	(b) (4)	
User entered empty.	Lorine Cook (b) (4)	13 Apr 2021 21:39:33
	(b) (4)	

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Farmers Branch'	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Texas'	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	09 Mar 2021 20:57:46
	(b) (4)	
	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
	(b) (4)	
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:23
	(b) (4)	
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4)	
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
User entered '05/Mar/2021 15:10'	(b) (4) System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

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Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	09 Mar 2021 20:57:46
	(b) (4)	
	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
	(b) (4)	
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:23
	(b) (4)	
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4)	
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Texas'	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

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Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
User entered '08/Mar/2021 09:12'	(b) (4) System	08 Mar 2021 14:12:15

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 15:40:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 14:12:15

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Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	09 Mar 2021 20:57:46
	(b) (4)	
	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
	(b) (4)	
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:23
	(b) (4)	
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4)	
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered '15/Mar/2021 11:40'	(b) (4) System	15 Mar 2021 15:40:37

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:39:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:40:37

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Farmers Branch'	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	25 Mar 2021 13:30:20
User entered '25/Mar/2021 06:26'	(b) (4) System	25 Mar 2021 13:26:01

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:39:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	25 Mar 2021 13:30:20
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:26:01

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Texas'	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:42
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User entered '09/Apr/2021 09:44'	(b) (4) System	09 Apr 2021 16:44:31

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:39:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:28:45
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User entered 'I'	(b) (4) Porsha Ford (b) (4) (b) (4)	09 Apr 2021 16:44:31

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:40
User entered '15/Apr/2021 14:39'	(b) (4) System	15 Apr 2021 18:39:43

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:15:18
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:40
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 18:39:43

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	09 Mar 2021 20:57:46
	(b) (4)	
	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
	(b) (4)	
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:23
	(b) (4)	
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4)	
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Texas'	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '16/Apr/2021 09:15'	(b) (4) System	16 Apr 2021 13:15:14

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:15:18
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 13:15:14

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Farmers Branch'	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered '19/Apr/2021 06:07'	(b) (4) System	19 Apr 2021 13:07:56

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:46:26
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:34:59
User signature succeeded.	Michele Reynolds (b) (4)	19 Apr 2021 13:13:19
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:07:56

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:10:02
User entered '21/Apr/2021 09:42'	System	21 Apr 2021 13:43:01

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	21 Apr 2021 21:56:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:10:02
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:46:26
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 13:43:01

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Lorine Cook (b) (4)	09 Mar 2021 20:57:46
	(b) (4)	
	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:17
	(b) (4)	
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
	(b) (4)	
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:23
	(b) (4)	
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4)	
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User entered 'Farmers Branch'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User entered 'Texas'	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

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Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:28:45
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:25
User entered '22/Apr/2021 06:02'	(b) (4) System	22 Apr 2021 13:02:28

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 19:25:18
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 21:28:45
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:25
User entered 'I'	Porsha Ford (b) (4)	22 Apr 2021 13:02:28

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'USA-US212-2021-MRNA-1273-P301000006'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Yes (Y)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'No (N)'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Jennifer'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:49
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:34
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Michele' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:22:57
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Jennifer'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:08
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Michele' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Jennifer'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered 'Bashour'	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:51
Query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:40
Signature has been broken.	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User entered 'Reynolds' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please update to appropriate PI name. Currently reflecting Sub-I name, incorrectly. ' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User closed query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:03
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	System	08 Mar 2021 14:12:15
User entered 'Bashour'	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please update to appropriate PI name.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:17
Un-reviewed for Safety.	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User entered 'Reynolds' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please update to appropriate PI name.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:10:29
User entered 'Bashour'	System	05 Mar 2021 15:10:02

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:53
User entered '9 MEDICAL PARKWAY PLAZA 4 SUITE 202' reason for change: Data Entry Error	Lorine Cook (b) (4)	09 Mar 2021 20:57:58
Query 'Please complete field - currently missing data.' answered with 'updated' (Site from CRA).	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:46
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '9 Medical Parkway Plaza \$ Suite 202' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:24
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4) System	08 Mar 2021 14:12:15
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:11:47
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:52:23
User entered '9 Medical Pkwy. Plaza 4, Suite 202'	lynn yauch (b) (4) (b) (4)	05 Mar 2021 19:51:54
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:39:25

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:55
Query 'Please complete field - currently missing data.' answered with 'Updated' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:07
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'Dallas' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:32
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Farmers Branch'	lynn yauch (b) (4)	05 Mar 2021 19:52:29
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:30

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:08:58
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:13
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered 'TX' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:47
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'Texas'	lynn yauch (b) (4)	05 Mar 2021 19:52:34
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:35

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:50:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:40:24
Signature has been broken.	System	15 Mar 2021 15:38:04
User entered empty.	System	15 Mar 2021 15:38:04
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:20
User closed query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:09:01
Query 'Please complete field - currently missing data.' answered with 'Updated ' (Site from CRA).	Lorine Cook (b) (4)	09 Mar 2021 20:58:18
Signature has been broken.	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User entered '75234' reason for change: Data Entry Error	(b) (4) Lorine Cook (b) (4)	09 Mar 2021 20:57:17
User opened query 'Please complete field - currently missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User closed query 'Please enter missing data.' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 23:23:51
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	08 Mar 2021 14:12:15
Reviewed for Safety.	System	08 Mar 2021 14:12:15
Query 'Please enter missing data.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered '75234'	lynn yauch (b) (4)	05 Mar 2021 19:52:39
User opened query 'Please enter missing data.' (Site from CRA).	(b) (4) lynn yauch (b) (4)	05 Mar 2021 19:51:54
	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:39:41

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Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:38
User signature succeeded.	Michele Reynolds (b) (4)	08 Mar 2021 14:34:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:11:47
User entered 'US'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:23:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	23 Apr 2021 19:25:34
User entered '10'	System	22 Apr 2021 13:02:28
User entered '9'	System	21 Apr 2021 13:43:01
User entered '8'	System	19 Apr 2021 13:07:56
User entered '7'	System	16 Apr 2021 13:15:14
User entered '6'	System	15 Apr 2021 18:39:43
User entered '5'	System	09 Apr 2021 16:44:31
User entered '4'	System	25 Mar 2021 13:26:01
User entered '3'	System	15 Mar 2021 15:40:37
User entered '2'	System	08 Mar 2021 14:12:15
User entered '1'	System	05 Mar 2021 15:10:36

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 10:23:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:38:21
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:53
User entered '23/Apr/2021 12:25'	(b) (4) System	23 Apr 2021 19:25:34

US3922080

Folder: SAE USA-US212-2021-MRNA-1273-P301000006

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 10:23:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:38:21
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:25:34